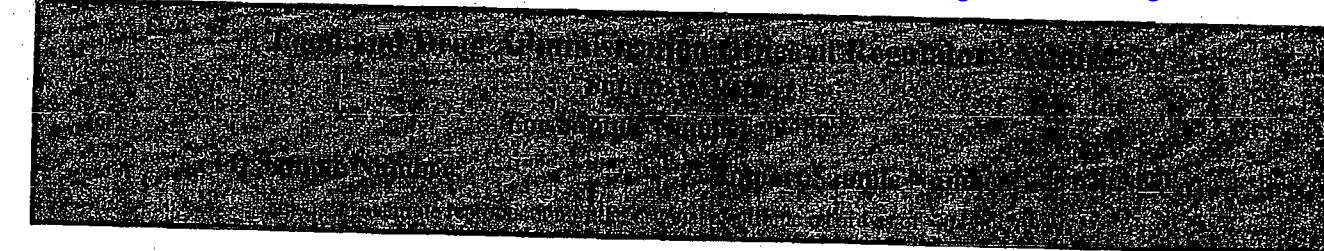


EXHIBIT 34



Sample Class: Normal Everyday Sample
Survey Sample

Home District:

Sample Origin: Domestic

Sample Type: Official

Orig C/R and Records To: DAL-DO

Sample Basis: Surveillance

Collecting District: DET-DO

Collection PACs: 56008A

Product Name: Digoxin (Cardiotonic); Human - Rx/Single Ingredient; Prompt Release Tablets

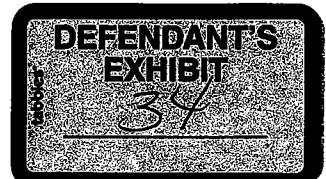
Product Description: 100 x 0.25mg Digoxin Tablets, USP

Collection Reason: The sample was collected as per memo for the FY 2008 Low Cost Generic Drug Sample Survey # 2008-800 (CP 7356.008) and is being reported in FACTS under Assignment # 896688 and Op # 3518061.

Lab: NRL District Conclusion:	Split Num 0	Date Received: 12/18/2007 District Conclusion Made By:	Date Out of Lab: 04/29/2008 District
Disposition Reason:		Disposition Authorized By:	Disposition Authorized Date
Performing Org NRL-DCB-G	PAC 56008A	LID PAF DRT	Compliance No Lab Class-Description 1 - In Compliance
Lab Conclusion The product meets specifications for Identification, Dissolution and Content Uniformity.	Lab Conclusion Made By Mathew, Samuel K		Laboratory Status Completed
Lab Conclusion Date 04/29/2008			

Date: 04/30/2008

Page: 1 of 1



Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 448892

This is an accurate reproduction of the original electronic record as of: 12/14/2007

Flag	Flag Remarks				
Survey Sample	FY 2008 Low Cost Generic Drug Sample Survey # 2008-800				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Surveillance	Official	0882662	Completed
FEI 1610608	Date Collected 12/03/2007	Product Code 63FCA06	Responsible Firm Shipper	PAC 56008A	Hours 2
Compliance Num	Country of Origin United States				
Related Smpl Num	Position Class INV	Sampling District DET-DO	NDC Number 62794-146-01	Permit Number	Storage Rqrmnt. Ambient
Dealer is Consumer No	Crx/DEA Schedule	Recall Num	Consumer Compl. Num Digitek	Brand Name	

Product Description

100 x 0.25mg Digoxin Tablets, USP

Product Label

See continuation.

Reason for Collection

The sample was collected as per memo for the FY 2008 Low Cost Generic Drug Sample Survey # 2008-800 (CP 7356.008) and is being reported in FACTS under Assignment # 896688 and Op # 3518061.

MFG Codes
70664A1Expiration Date
Aug 2009

Firm Legal Name

UDL Laboratories, Inc

Address
12720 Dairy Ashford Rd Sugar Land, TX
77478-2844 USType of Firm
ShipperFirm FEI
1610608

Actavis Totowa LLC

101 E Main St Little Falls, NJ 07424-5608

Manufacturer

FCE
2244683Wal-Mart Pharmacy Warehouse
#6028801 Corda Blvd Crawfordsville, IN 47933-
2152 US

Dealer

FCE
3004344335

Size of Lot

(b) (4) x 100 count bottles

Est. Value
FDA484

Rept Type

Carrier Name

Date Shipped

Description of Sample

The sample consists of 2 x 100 count 0.25mg Digitek (Digoxin Tablets, USP) with NDC # 62794-146-01 and assigned lot # 70664A1 and expiry date 8/2009.

Method of Collection

2 x 100 count bottles of 0.25mg Digitek (Digoxin Tablets, USP) lot 70664A1 were randomly selected from shelf.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"Sample # 448892 EB 12/3/07"

Collector's Identification on Seal

"448892 Ernest Bizjak 12/3/07"

Sample Delivered To

FEDEX

Date Delivered

12/17/2007

Orig C/R & Records To

DAL-DO

Lab w/Split Sample

0

Lab

NRL

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 448892

This is an accurate reproduction of the original electronic record as of 12/14/2007

Document Number	Document Date	Document Type	Document Remarks
	12/03/2007	Other	FDA-482; 1 page
	12/03/2007	Other	FDA-484; 4 pages

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
	No Charge	No	No	Ernest Bizjak

Name of Signer	Date & Time of Signature	Meaning
Ernest Bizjak	12/14/2007 09:15 AM ET	Collector

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 448892

This is an accurate reproduction of the original electronic record as of 12/14/2007

Continuation:

Product Label

The white HDPE bottle with matching screw cap is labeled in part "NDC 62794-146-01 *** DIGITEK (digoxin tablets, USP) *** 250mcg (0.25 mg) *** 100 TABLETS *** Distributed by: BERTEK PHARMACEUTICALS INC. Sugar Land, TX 77478 *** Manufactured by: AMIDE PHARMACEUTICAL, INC. 101 East Main Street Little Falls, NJ 07424 USA *** Control No.: 70664A1 *** Exp. Date: Aug 09".

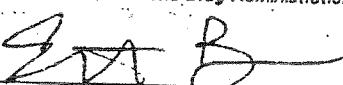
How Prepared

The 2 bottles were identified as per Collector's ID and placed into a clear Whirl-pak bag that was then officially sealed at the dealer. The sample was transported back to the DET-DO/INDY-RP where it was stored in a locked sample cabinet at ambient conditions until it was boxed and shipped to lab.

Remarks

Per assignment memo, test sample for UDU, Diss, and ID. All analytical methods are compendial.

Dena McClamroch, General Manager stated that she could not provide a dollar value for the sample. If this information is needed, contact Monty Mason, Pharmacy Director at ph#479-277-1558.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO. DET-DO # 312-327-8100 300 Austin Hwy, Suite 5900 Detroit, MI 48207
2. NAME AND TITLE OF INDIVIDUAL Dena M. McHamrock		3. DATE 12/3/07
TO	4. FIRM NAME Wal-Mart	4. HOUR 9:25 a.m.
	6. NUMBER AND STREET 801 Cor-ck Blvd.	5. HOUR p.m.
7. CITY AND STATE & ZIP CODE Crawfordsville, IN 47933		8. PHONE # & AREA CODE (765) 361-4922
Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)] ¹ and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264] ²		
9. SIGNATURE (Food and Drug Administration Employee(s)) 		10. TYPE OR PRINT NAME AND TITLE (FDA Employee(s)) Ernest Bizjak, Investigator
<p>¹Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:</p> <p>Sec. 704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein <i>including records, files, papers, processes, controls, and facilities</i> bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data <i>other than data as to qualifications of technical and professional personnel performing functions subject to this Act</i>, and research data <i>other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title</i>. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.</p> <p>Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.</p> <p>Section 704 (f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.</p> <p>Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by</p>		
<p>order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.</p> <p>(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.</p> <p>²Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:</p> <p>Part F - Licensing - Biological Products and Clinical Laboratories and*****</p> <p>Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."</p> <p>Part F - *****Control of Radiation.</p> <p>Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests <i>for testing programs</i> required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."</p> <p>(b) "Every manufacturer of electronic products shall establish and maintain such records <i>(including testing records)</i>, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards pre-scribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a).*****</p>		

DET - DO # 313-393-8100

300 River Place, Suite 5900

Detroit, MI 48207

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

2. NAME AND TITLE OF INDIVIDUAL

Dena M. McClamroch, General Manager

3. DATE

12/3/07

4. SAMPLE NUMBER

See below

5. FIRM NAME

Wal-Mart

6. FIRM'S DEA NUMBER

7. NUMBER AND STREET

861 Cor-ck Blvd

8. CITY AND STATE (Include Zip Code)

Crawfurdville, IN 47933

9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(c)) and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act (21 USC 360i(b)) and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.

(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)

Sample #414930 consists of ① 2 x 100 bottles Captopril Tablets, 12.5 mg, lot DG10952 with NDC # 64671-902-01

② Sample #414931 consists of 53 x 3.5g tubes Erythromycin Ophthalmic Ointment, 5mg/g, lot P53 with NDC # 0168-0070-38

③ Sample #414932 consists of 2 x 100 bottles Hydrochlorothiazide Capsules, 12.5 mg, lot 350713 with NDC # 0378-0810-01

④ Sample #414933 consists of 2 x 100 bottles Estradiol Tablets, 0.5 mg, lot 304344 with NDC # 0555-0899-02

⑤ Sample #414934 consists of 2 x 100 bottles Atorvast Tablets, 25 mg, lot 1S1437 with NDC # 0378-0218-01

⑥ Sample #414935 consists of 1 x 500 bottle Amoxicillin Capsules, 250 mg, lot # 022011 with NDC # 0781-2020-05

⑦ Sample #414936 consists of 2 x 100 bottles Endo-Pr.1 Maltate Tablets, 2.5 mg, lot # 27875 with NDC # 0093-0026-01

⑧ Sample #414937 consists of 22 bottles Amoxicillin for Oral Suspension, 200 mg/5mL, lot # 7955794, NDC # 63304-969-03

10. SAMPLES WERE

PROVIDED AT NO CHARGE
 PURCHASED
 BORROWED (To be returned)

11. AMOUNT RECEIVED FOR SAMPLE

NO CASH BILLED
 CREDIT CARD VOUCHER

12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.)

Dena McClamroch

13. COLLECTOR'S NAME (Print or Type)

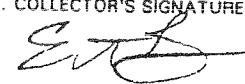
Ernest Biegak

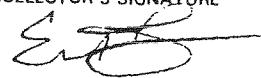
14. COLLECTOR'S TITLE (Print or Type)

Inventory

15. COLLECTOR'S SIGNATURE

EB

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		1. DISTRICT, ADDRESS & PHONE NUMBER DET. DO #313-393-8100 300 River Place, Suite 5900 Detroit, MI 48207
2. NAME AND TITLE OF INDIVIDUAL Dena M. McClanrock, Grant Manager		3. DATE 12/3/07
4. SAMPLE NUMBER 45cc below *		
5. FIRM NAME iVAC-Mast		6. FIRM'S DEA NUMBER
7. NUMBER AND STREET 801 Cor-ida Blvd.		8. CITY AND STATE (Include Zip Code) Crawfordsville, IN 47933
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)		
<p>The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.</p> <p>(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)</p> <p>(S) Cloridine EB 12/3/07</p>		
<p>(9) Sample #448877 consists of 3x90 boxes Cloridine HCl Tablets, 0.1mg, lot 7M833, NDC # 51079-299-62</p> <p>(10) Sample #448878 consists of 2x100 bottles Bisoprolol Fumarate / Hydrochlorothiazide Tablets, 2.5/6.25 mg, lot 1S0806 with NDC # 0378-0501-01</p> <p>(11) Sample #448879 consists of 53x15g tubes Gentamicin Sulfate Ointment, 0.1%, lot Z176 with NDC # 0168-0078-15</p> <p>(12) Sample #448880 consists of 2x100 bottles Glyburide Tablets, 2.5mg, lot 1493474 with NDC # 0093-8343-61</p> <p>(13) Sample #448881 consists of 2x100 bottles Digitok (Digoxin) Tablets, 0.125mg, lot 70298A1 with NDC # 62794-145-01</p> <p>(14) Sample #448882 consists of 7x30 bottles Citalopram HBr Tablets, 20mg, lot C72275 with NDC # 55111-343-30</p> <p>(15) Sample #448883 consists of 83x5mL bottles Gentamicin Sulfate Ophthalmic Solution, 3mg/mL, lot 729553F n.H. NDC # 61314-632-05</p> <p>(16) Sample #448884 consists of 2x100 bottles Ciprofloxacin Tablets, 250mg, lot # 1717002 with NDC # 63304-709-01 28-12-10</p>		
10. SAMPLES WERE <input checked="" type="checkbox"/> PROVIDED AT NO CHARGE <input type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)		11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> NO CASH <input type="checkbox"/> BILLED <input type="checkbox"/> CREDIT CARD <input type="checkbox"/> VOUCHER
13. COLLECTOR'S NAME (Print or Type) Ernest Buzjak		14. COLLECTOR'S TITLE (Print or Type) Investigator
15. COLLECTOR'S SIGNATURE 		

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER DET. DO # 313-393-8100 300 River Place; Sut. 5100 Detroit, MI 48207	
2. NAME AND TITLE OF INDIVIDUAL Dena M. McCamroch, General Manager		3. DATE 12/3/07	4. SAMPLE NUMBER *see below
5. FIRM NAME WFM-Mart		6. FIRM'S DEA NUMBER	
7. NUMBER AND STREET 801 Cor-Dr. Blvd.		8. CITY AND STATE (Include Zip Code) Crawfordsville, IN 47933	
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)			
<p>The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.</p> <p>(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)</p>			
<p>(17) Sample # 448885 consists of 2x100 bottles Erythrocin Tablets, 250 mg, lot 56753AF22 with NDC # 0074-6246-20</p> <p>(18) Sample # 448886 consists of 2x100 bottles Acyclovir Capsules, 200 mg, lot 35300555A with NDC # 0093-8940-01</p> <p>(19) Sample # 448887 consists of 2x100 bottles Bumetanide Tablets, 0.5 mg, lot 1V76033 with NDC # 0093-4232-01</p> <p>(20) Sample # 448888 consists of 2x100 bottles Doxazosin Mesylate Tablets 1mg, lot 3000793 with NDC # 0378-4021-01</p> <p>(21) Sample # 448889 consists of 2x100 bottles Famotidine Tablets, 20mg, lot BEB02A with NDC # 0172-5728-60</p> <p>(22) Sample # 448890 consists of 53x3 5g tubes Bacitracin Ophthalmic Ointment, 500 U/g, lot P72 with NDC # 0168-0026-38</p> <p>(23) Sample # 448891 consists of 54x20mL bottles Albuterol Sulfate Inhalation Solution, 0.5%, lot 157641, with NDC # 24208-347-20</p> <p>(24) Sample # 448892 consists of 2x100 bottles Digitek (Digoxin) Tablets, 0.25mg lot 70664A1, with NDC # 62794-146-01</p>			
10. SAMPLES WERE <input checked="" type="checkbox"/> PROVIDED AT NO CHARGE <input type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)		11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> CASH <input type="checkbox"/> VOUCHER <input type="checkbox"/> BILLED <input type="checkbox"/> CREDIT CARD	
13. COLLECTOR'S NAME (Print or Type) Ernest Brink		14. COLLECTOR'S TITLE (Print or Type) Investigator	
15. COLLECTOR'S SIGNATURE 			

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER DET. 50 #313-393-8100 300 River Place, Suit. 5900 Detroit, MI 48207
2. NAME AND TITLE OF INDIVIDUAL Dina M. McHamrock, General Manager		3. DATE 12/3/07
4. SAMPLE NUMBER *see below*		
5. FIRM NAME Wal-Mart	6. FIRM'S DEA NUMBER	
7. NUMBER AND STREET 801 Cor-ea Blvd.	8. CITY AND STATE (Include Zip Code) Crawfordsville, IN 47933	
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)		
<p>The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360i(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.</p> <p>(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)</p> <p>(25) Sample # 448893 consists of 2x100 bottles Diltiazem HCl Tablets, 30mg, lot D01047 with NDC # 0093-0318-01</p> <p>(26) Sample # 448894 consists of 1x1000 bottles Amitriptyline HCl Tablets, 10mg, lot 1P5678 with NDC # 0378-2610-10</p> <p>(27) Sample # 448895 consists of 2x100 tablets Epitol (Carbamazepine) Tablets, 200mg, lot 211870 with NDC # 0093-0090-01</p> <p>(28) Sample # 448896 consists of 2x100 capsules Fluoxetine Capsules, 10mg, lot 148748A with NDC # 0093-1042-01</p>		
<p>These samples were provided free of charge.</p>		
10. SAMPLES WERE <input checked="" type="checkbox"/> PROVIDED AT NO CHARGE <input type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)	11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> NO CASH BILLED <input type="checkbox"/> VOUCHER CREDIT CARD (None)	12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge) Dina M. McHamrock
13. COLLECTOR'S NAME (Print or Type) Ernest B. Zajic	14. COLLECTOR'S TITLE (Print or Type) Investigator	15. COLLECTOR'S SIGNATURE ETZ

FLAG Original

ANALYST WORKSHEET		1. PRODUCT DIGITEK (digoxin tablets, USP) 250 mcg (0.25 mg)			2. SAMPLE NUMBER 448892
3. SEALS	<input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN	4. DATE REC'D 2/4/08	5. RECEIVED FROM Howard Lynch	6. DISTRICT OF LABORATORY NRL	
7. DESCRIPTION OF SAMPLE					

One clear, plastic bag officially sealed, "448892 12/3/07 Ernest Bizjak Investigator", containing two product bottles each identified "448892 ES 12/3/07". An FDA 525 is attached to the sample.

8. NET CONTENTS	<input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED in 448892 <input checked="" type="checkbox"/> UNITS EXAMINED	DECLARE/UNIT AMOUNT FOUND % OF DECLARED	100 tablets — —	9. LABEL- ING	1. ORIGINAL(S) SUBMITTED COPIES SUBMITTED <input type="checkbox"/> NONE
10. SUMMARY OF ANALYSIS					

Container: Round, opaque, white, plastic bottle with a similar, screw-on, safety cap. Safety-seal beneath cap is intact. Bottle is approximately 4 cm. in diameter and 7.5 cm. in height.

Labeling: Commercially-printed, rectangular, paper, stick-on label. Commercially-printed product insert is inside bottle.

Code: "Control No.: 70664A1" and "Exp. Date: AUG 09" printed on each bottle label.

Product: Round, biconvex, solid, white tablet. Tablet is unscored on one side with no markings. Opposite side is 1/2-scored with markings "B" and "146". Tablet is approximately 7 mm. in diameter.

Analysis: Identification, Dissolution, and Content Uniformity.

Method: USP 30 - NF 25, p. 1943.

Results: See general continuation sheet page 2.

11. RESERVE SAMPLE

Original plastic bag containing one open and one intact product bottle. Bag is officially sealed "448892 ~~4/29/08~~ Valentino Fiorella Analyst". Open bottle is identified "448892 VF 2/4/08" and "DPD 4/25/08". Sample returned to the sample custodian.

12.a. ANALYST SIGNATURE (Broke Seal <input checked="" type="checkbox"/>) <i>Valentino Fiorella</i>	13. WORK-SHEET CHECK	a. BY <i>S. Mathew</i>
b. <i>Dong ping Dai</i>		b. DATE <i>4/29/08</i>
c.	14. DATE REPORTED	<i>4/29/08</i>

GENERAL CONTINUATION SHEET	PRODUCT	SAMPLE NO.
Digoxin Tablets (0.25 mg)		448892
RESULTS:		
Identification		
<p>The retention time of the major peak in the chromatogram of the <i>sample preparation</i> corresponds to that in the chromatogram of the <i>standard preparation</i>. <u>Complies</u></p>		
Content Uniformity		
<p>(See computer printout pages 6 - 7 for complete results)</p>		
<p>Range: <u>95.2</u> % to <u>99.5</u> %; Average (X) : <u>97.8</u> %;</p>		
<p>RSD: <u>1.3</u> %; s: <u>1.23</u></p>		
<p>Acceptance Value (AV) = <u>3.7</u> %</p>		
<p>(Limit: AV ≤ 15.0 % unless otherwise specified in the individual monograph)</p>		
Dissolution		
<p>(See least squares line fitting page 11 for complete results)</p>		
<p>Range: <u>87.4</u> % to <u>101.4</u> % ; Avg.: <u>92.5</u> %</p>		
<p>(Limit: Each unit is NLT Q+5% (Q=80%) for 6 units tested (Stage 1))</p>		
ANALYST(S) <i>Valentino Morello</i>		ANALYST NO. 113
PAGE <u>2</u> OF <u>11</u> PAGES		

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892
ANALYST(S) <i>Valentino Fiorella</i>	ANALYST NO. 113	PAGE 3 OF 11 PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892

ANALYST(S) <i>Valentino Fiorella</i>	ANALYST NO. 113	PAGE 4 OF 11 PAGES
FORM FDA 431a (5/84)		

Statistical Analysis of Data:

Standard Solution 1 (CCV)

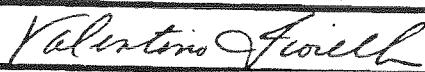
02/12/2008

Relative STD Deviation	0.29 %
Standard Deviation	3887.34041
Average (mean)	1358880
Number of entries	5
Range	1353155 To 1363224

Data Entered:

1353155
1358820
1361570
1357631
1363224

Analyst(s)



Analyst No.
113

Page 5 of 11 Pages

General Continuation
Sheet

Product: Digoxin Tablets

Sample No.

448892

Content Uniformity

02/13/2008

No. of Units Examined	10
Standard Weight	2.424 mg.
Standard Dilution	100
Sample Dilution	10

Data Entered:

Unit #1	1371299	STD #1	1358880
Unit #2	1357145	Blank	0
Unit #3	1361144		
Unit #4	1375129		
Unit #5	1333663		
Unit #6	1366084		
Unit #7	1377397		
Unit #8	1375557		
Unit #9	1389731		
Unit #10	1394609		

CONTENT UNIFORMITY RESULTS:

	FOUND (mg/tablet)	DECLARED	% of DECLARED
UNIT #1	0.245	0.25	97.8
UNIT #2	0.242	mg/tablet	96.8
UNIT #3	0.243		97.1
UNIT #4	0.245		98.1
UNIT #5	0.238		95.2
UNIT #6	0.244		97.5
UNIT #7	0.246		98.3
UNIT #8	0.245		98.1
UNIT #9	0.248		99.2
UNIT #10	0.249		99.5
AVG.	0.244		97.8

OFFICIAL LIMITS:	90.0	% TO	105.0	%
No. of Units Examined	10			
RANGE	95.2	% TO	99.5	% of Declared
UNITS >=85 BUT <=115 % of Avg. Limit	:			10
UNITS >=75 BUT <85 OR >115 BUT <=125 % of Avg. Limit	:			0
UNITS <75 OR >125 % of Avg. Limit	:			0
REL. STD. DEV. :	1.3	LIMIT <= 6.0%		

mg/unit = (R_spl * std_wt * spl_dil) / (R_std * std_dil * 1 unit)

Analyst(s)

Valentino Scioell

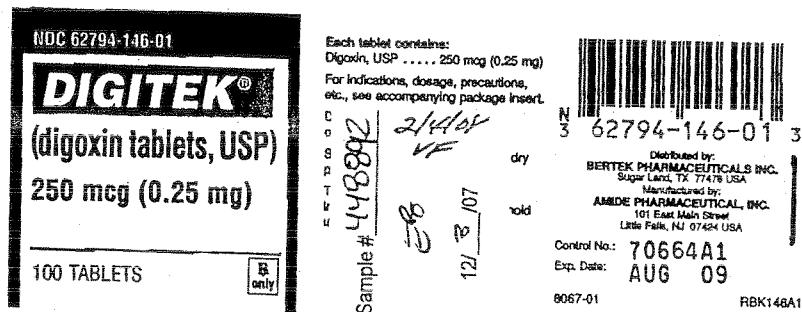
Analyst No.

113

Page 6 of 11 Pages

Digoxin Tablets (0.25 mg)
Spl.# 448892
2/4/08
VF

Labeling



Statistical Analysis of Data:**Content Uniformity
Standard Deviation**

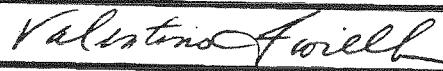
02/13/2008

Relative STD Deviation	1.26 %
Standard Deviation	1.23
Average (mean)	97.76
Number of entries	10
Range	95.2 To 99.5

Data Entered:

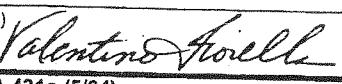
97.8
96.8
97.1
98.1
95.2
97.5
98.3
98.1
99.2
99.5

Analyst(s)

Analyst No.
113

Page 7 of 11 Pages

GENERAL CONTINUATION SHEET	PRODUCT	SAMPLE NO.
	Digoxin Tablets (0.25 mg)	448892
ANALYST(S)	ANALYST NO.	PAGE 8 OF 11 PAGES
<i>Valentino Fiorelli</i>	113	
FORM FDA 431a (5/84)		

GENERAL CONTINUATION SHEET	PRODUCT	SAMPLE NO.
	Digoxin Tablets (0.25 mg)	448892
ANALYST(S)	ANALYST NO.	PAGE 9 OF 11 PAGES
	113	
FORM FDA 431a (5/84)		

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892
ANALYST(S) <i>Valentino Gielle</i>	ANALYST NO. 113	PAGE 10 OF 11 PAGES
FORM FDA 431a (5/84)		

General Continuation
Sheet

Product: Digoxin Tablets (0.25 mg)

Sample No.

448892

Least Squares Line Fitting

04/25/2008

The Line Fitting used is $Y = mX + b$

with $m = 0.03663$
 and $b = -0.0548$
 Correlation Coefficient = 0.99984

Data Entered:

X	Y	LSLF y	% Deviation
20	0.661	0.6778	2.479
40	1.444	1.4104	2.382
60	2.133	2.143	0.467
80	2.862	2.8756	0.473
100	3.615	3.6082	0.188

Extrapolated Data:

	X	Y
Tab 1	88.9	3.203
	92.7	3.341
Tab 2	89.7	3.230
	90.4	3.258
Tab 3	103.0	3.719
	99.8	3.600
Tab 4	88.5	3.188
	86.2	3.101
Tab 5	91.7	3.304
	91.3	3.288
Tab 6	95.5	3.445
	91.8	3.309

Analyst(s)

*Dongping Dan*Analyst No.
000

Page // of // Pages

ATTACHMENT A - Page 1 of 20 pages

Product: Digoxin Tablets (0.25 mg)

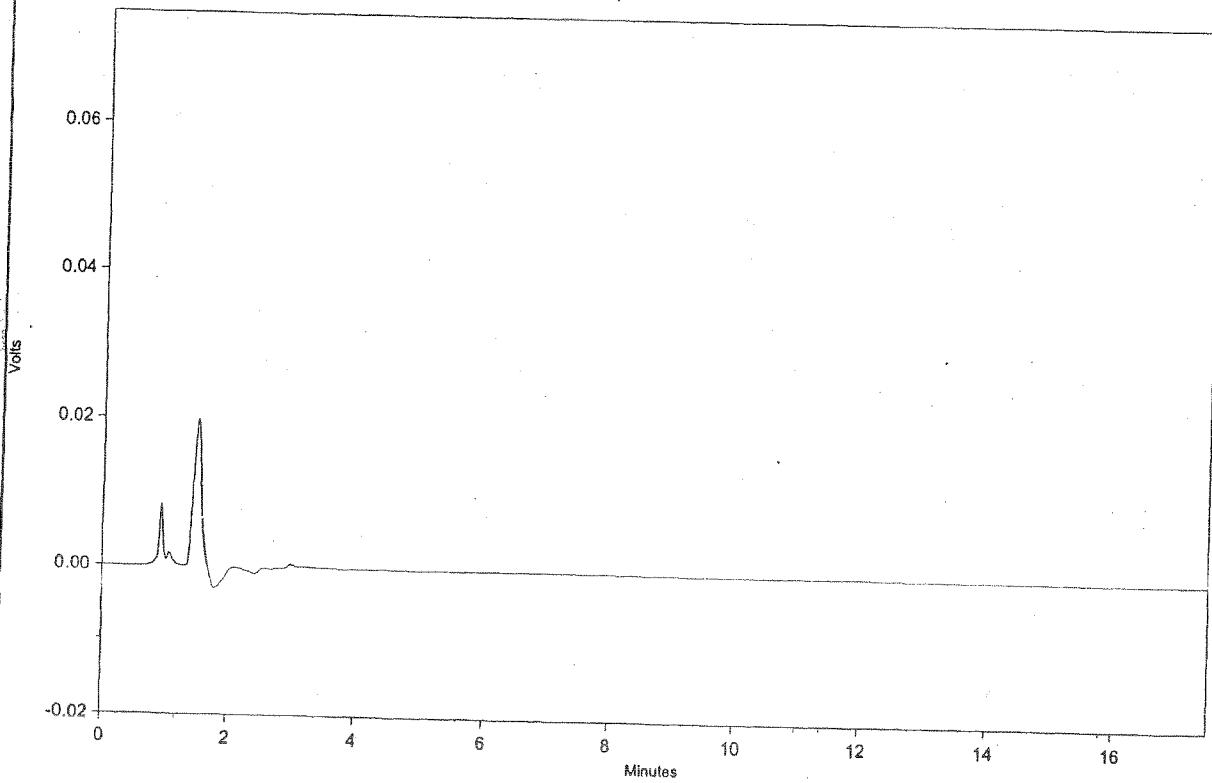
Spl.No. 448892

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 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Blank-Rep2
 Date: 02/12/2008 8:43:24 AM
 Vial: 0
 Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm, 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 2 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: System Suitability Solution

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\SysSuitSoln.

Date: 02/12/2008 9:02:22 AM

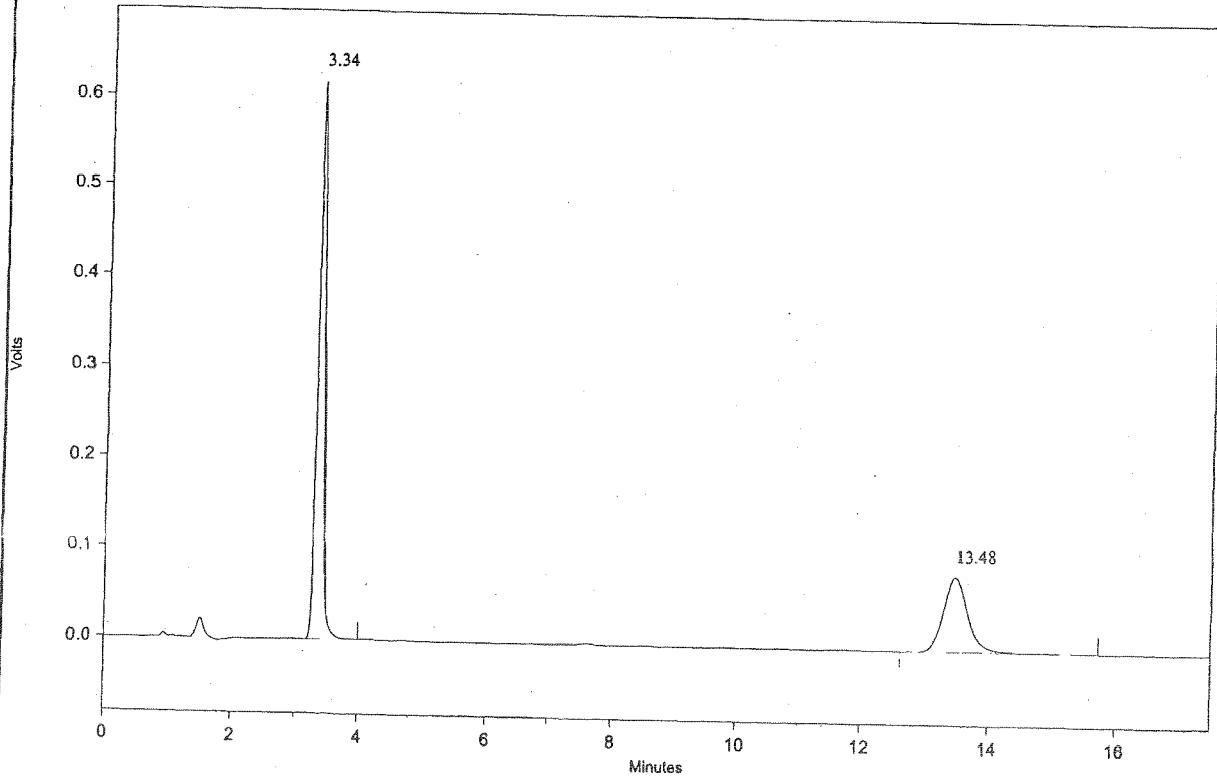
Vial: 1

Injection Volume: 50 μ l

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxigenin	3.34	4359467	618053	1.2	0.0	3134
2	Digoxin	13.48	2187380	82756	1.2	22.1	6321
Totals			6546847	700809			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 mL/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 3 of 20 pages

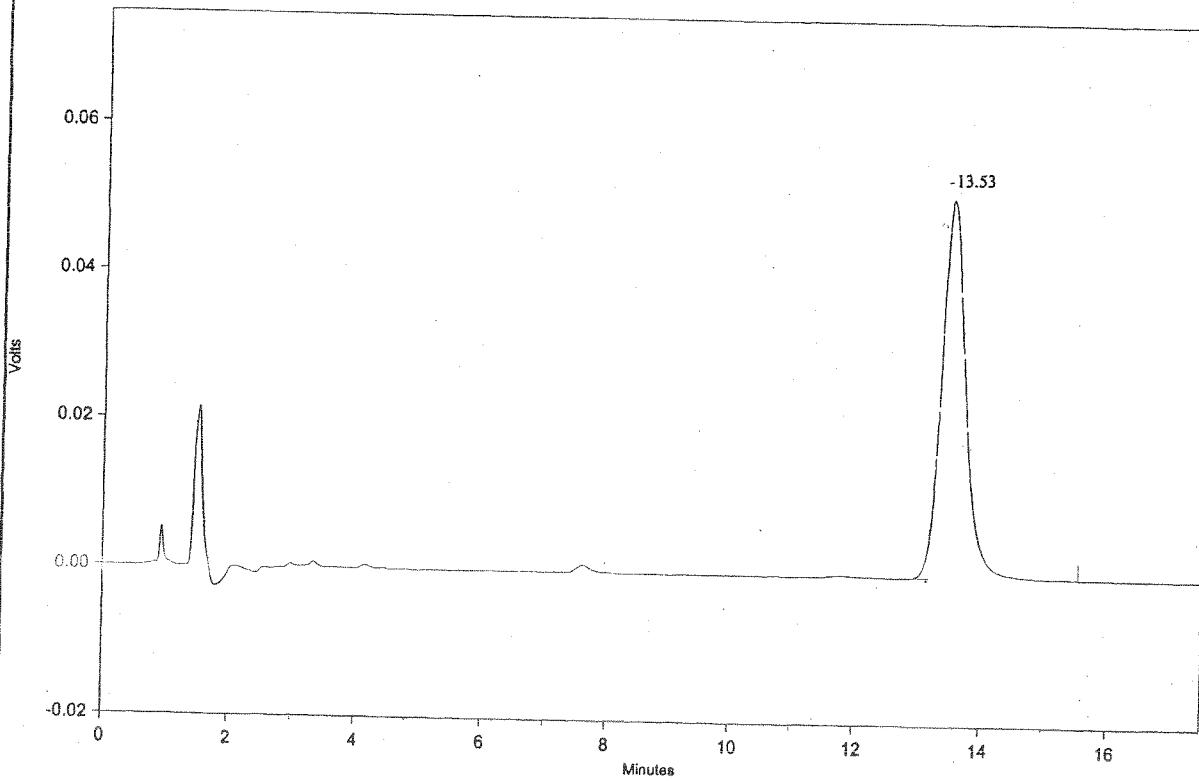
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep1.
 Date: 02/12/2008 9:24:02 AM
 Vial: 2
 Injection Volume: 50 μ l

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.53	1353155	51094		1.2	0.0
Totals			1353155	51094			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 4 of 20 pages

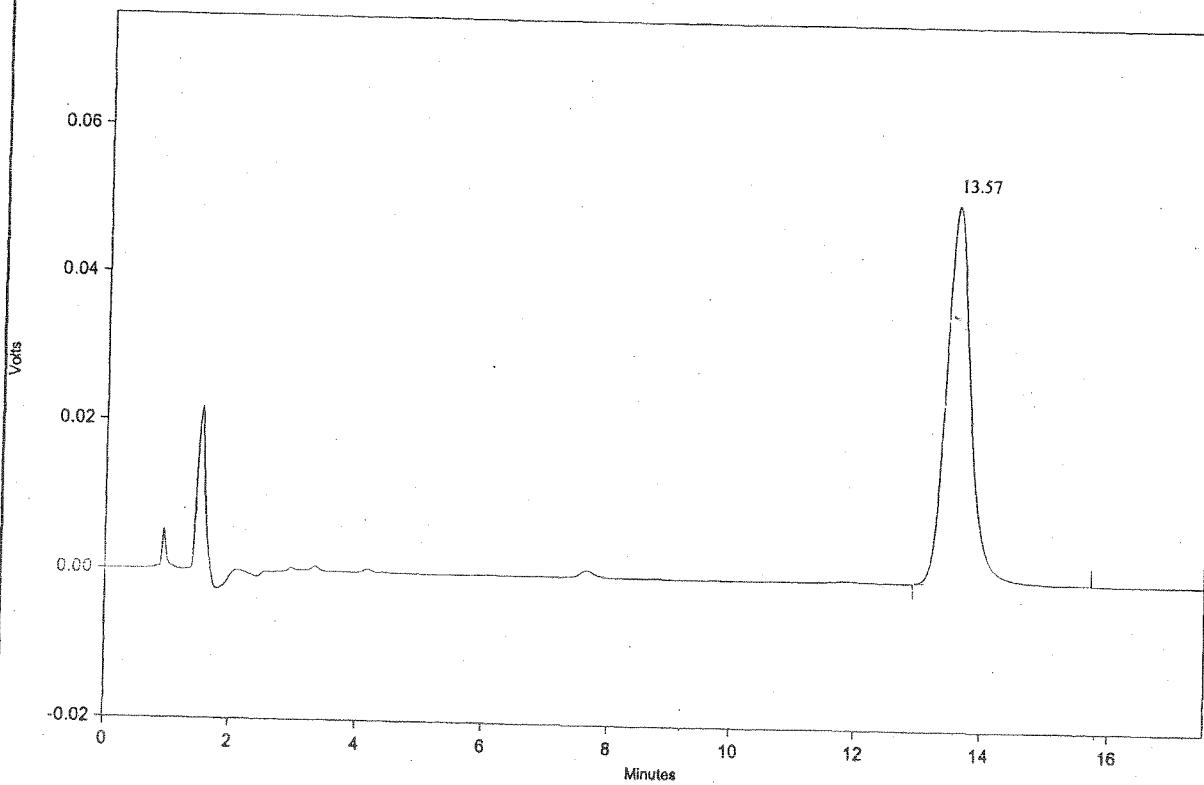
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep2.
 Date: 02/12/2008 9:43:01 AM
 Vial: 2
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.57	1358820	51067		1.2	0.0
Totals			1358820	51067			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 5 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep3.

Date: 02/12/2008 10:01:55 AM

Vial: 2

Injection Volume: 50 ul

Detector A

(218nm)

Pk #

Name

Retention Time

Area

Height

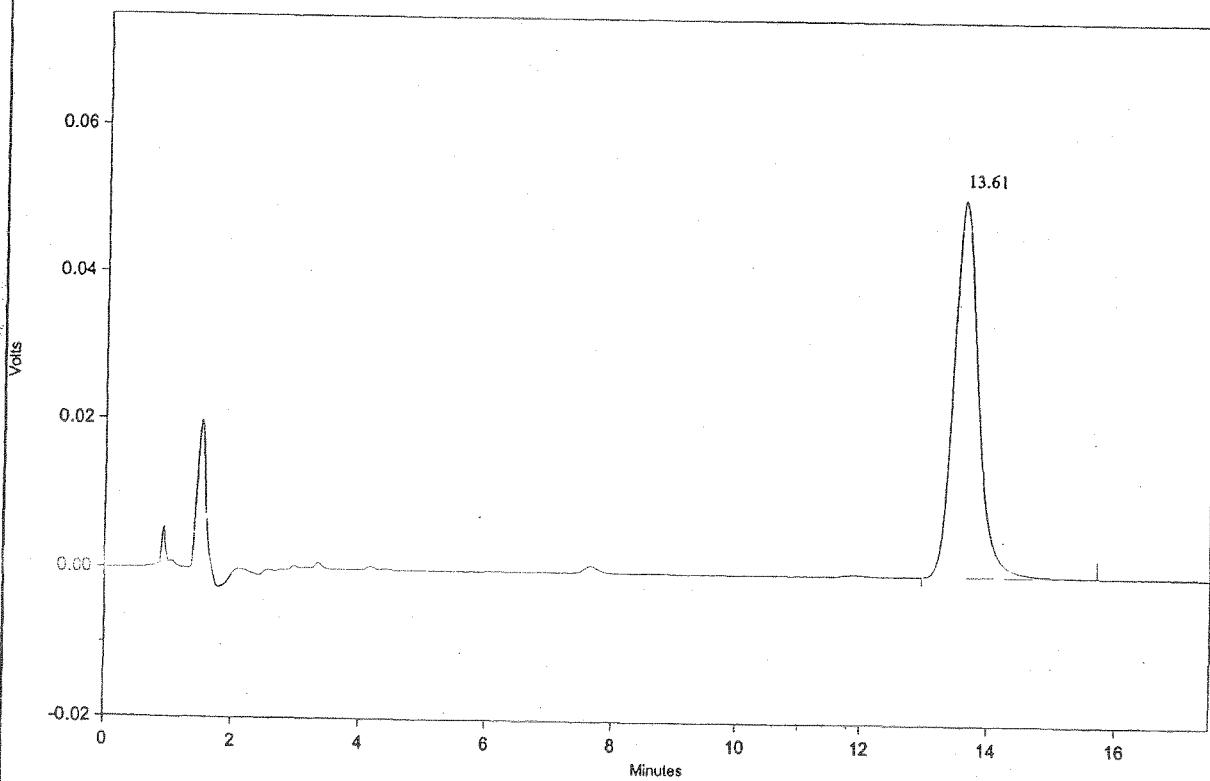
Asymmetry

Resolution

Theoretical plates

1	Digoxin	13.61	1361570	50892	1.2	0.0	6301
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Totals			1361570	50892			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 6 of 20 pages

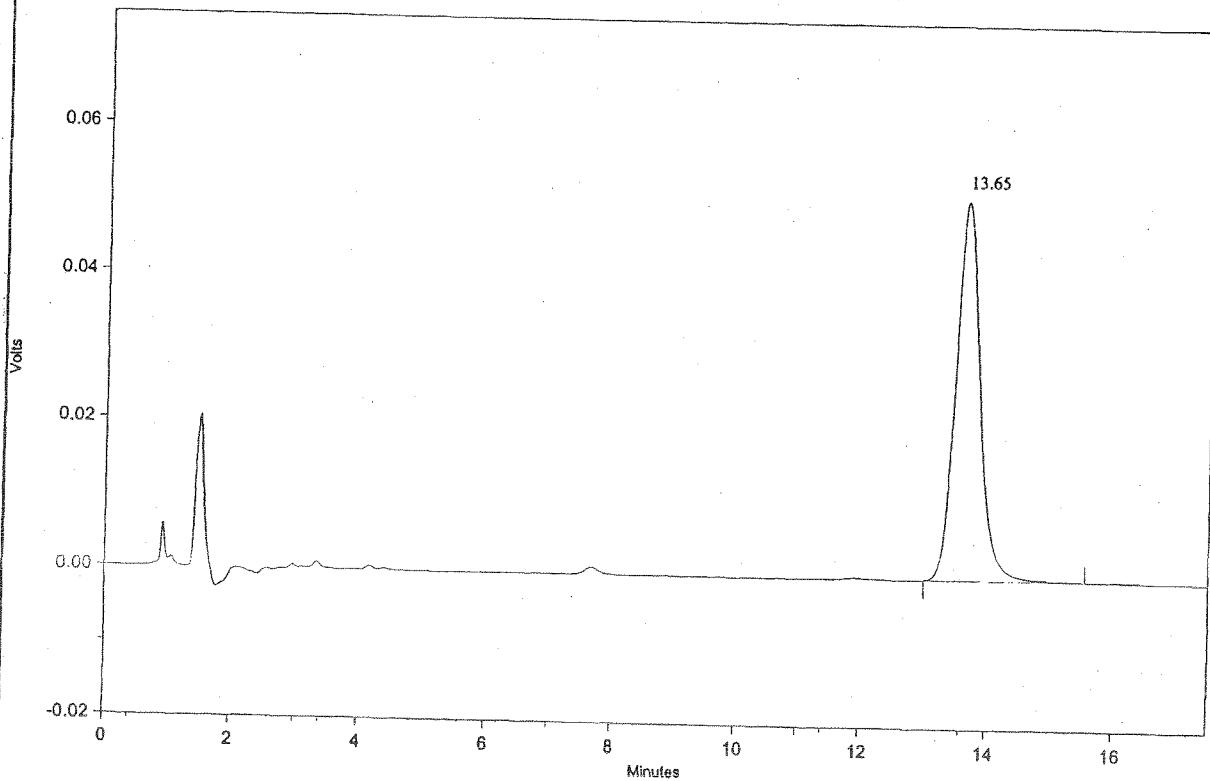
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)
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 Date: 02/12/2008 10:20:57 AM
 Vial: 2
 Injection Volume: 50 μ l

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.65	1357631	51144		1.2	0.0
Totals			1357631	51144			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 7 of 20 pages

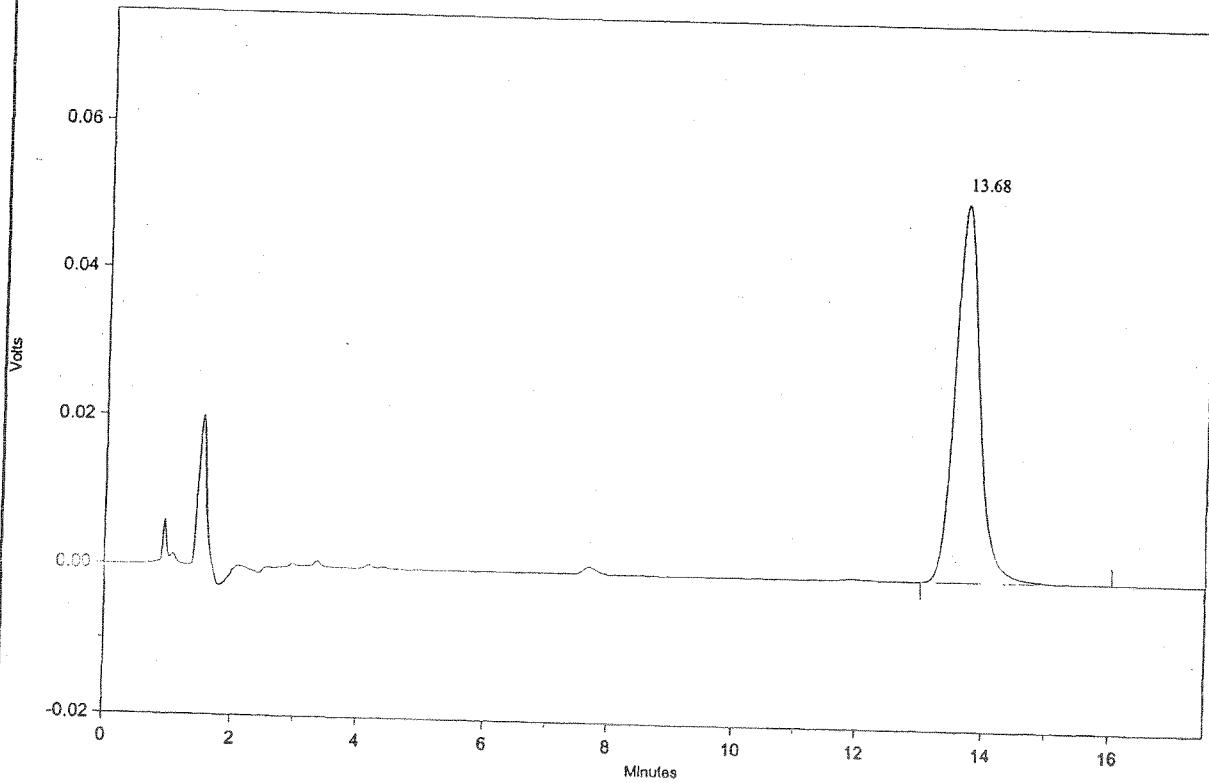
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep5.
 Date: 02/12/2008 10:39:55 AM
 Vial: 2
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.68	1363224	50989		1.2	0.0
Totals			1363224	50989			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 mL/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 8 of 20 pages

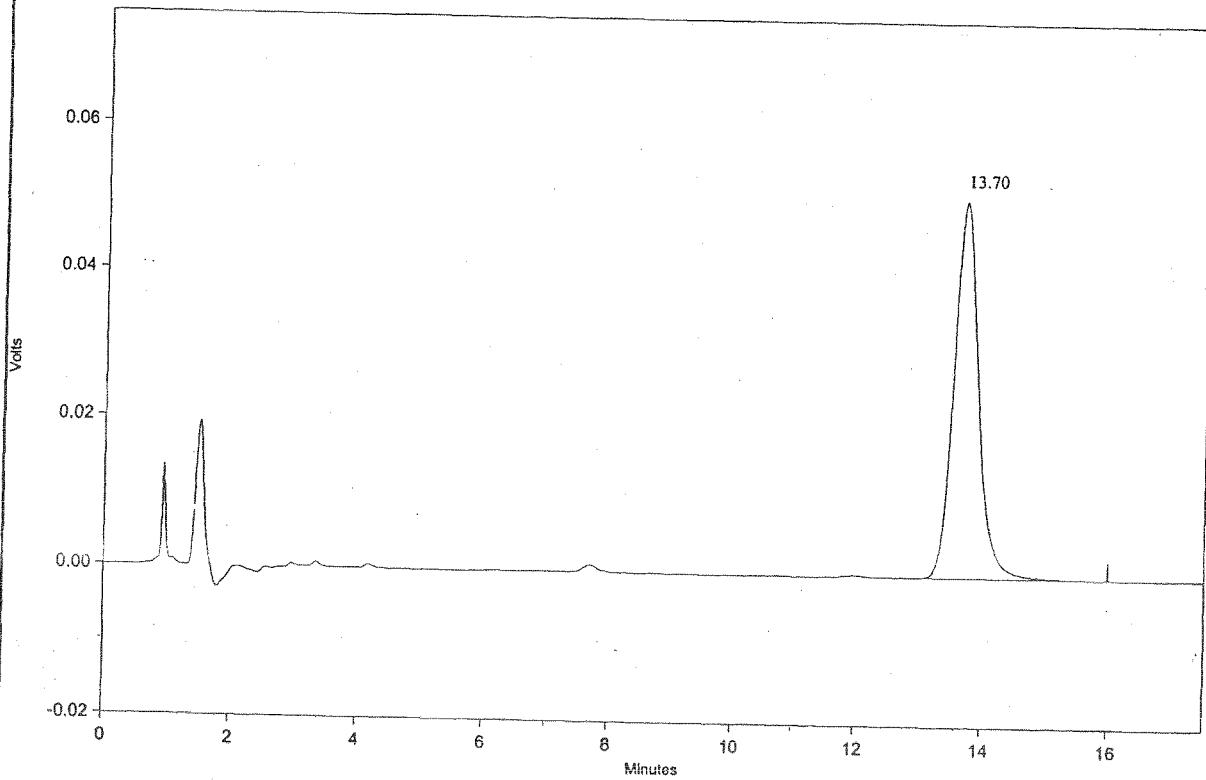
Product: Digoxin Tablets (0.25 mg)

SPL.No. 448892

Name: Standard Solution 2 (ICV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\CheckStd.
 Date: 02/12/2008 10:58:52 AM
 Vial: 3
 Injection Volume: 50 μ l

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.70	1355271	50836		1.2	0.0
Totals			1355271	50836			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 9 of 20 pages

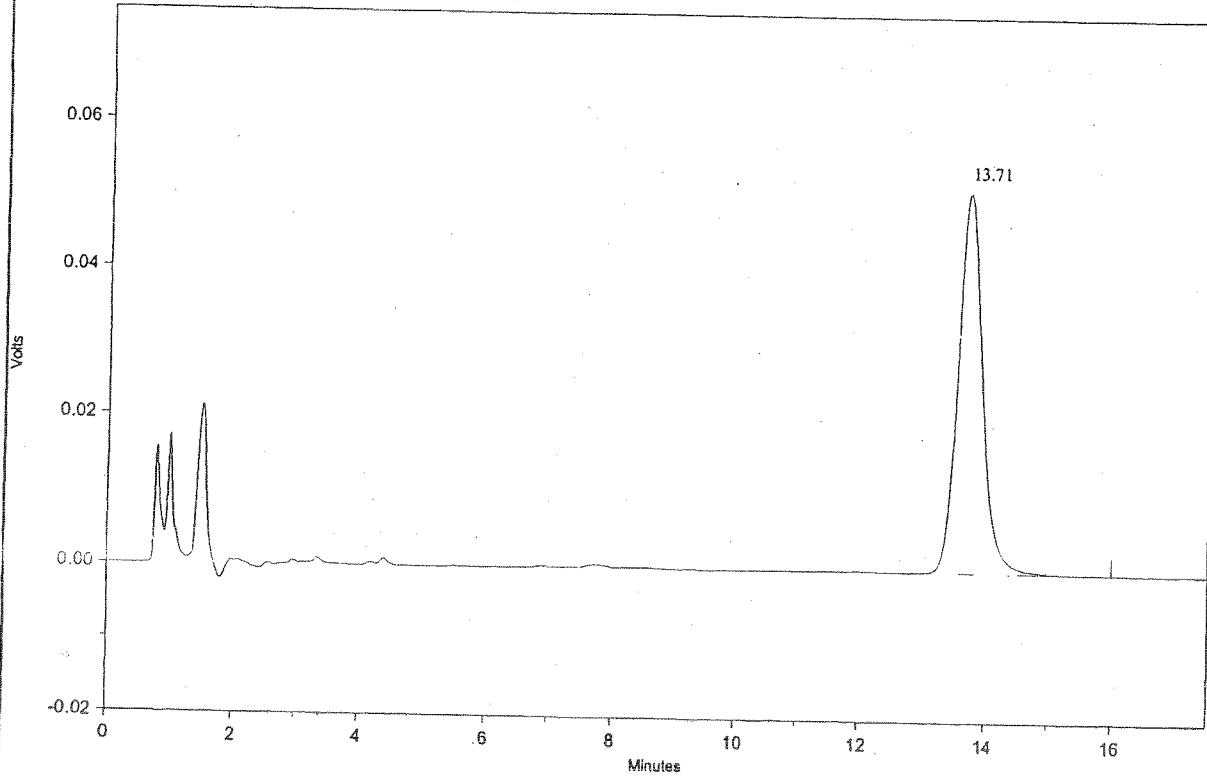
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 1
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 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab1
 Date: 02/12/2008 11:21:25 AM
 Vial: 4
 Injection Volume: 50 μ l

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.71	1371299	51389		1.2	0.0
Totals			1371299	51389			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 10 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 2

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab2

Date: 02/12/2008 11:42:46 AM

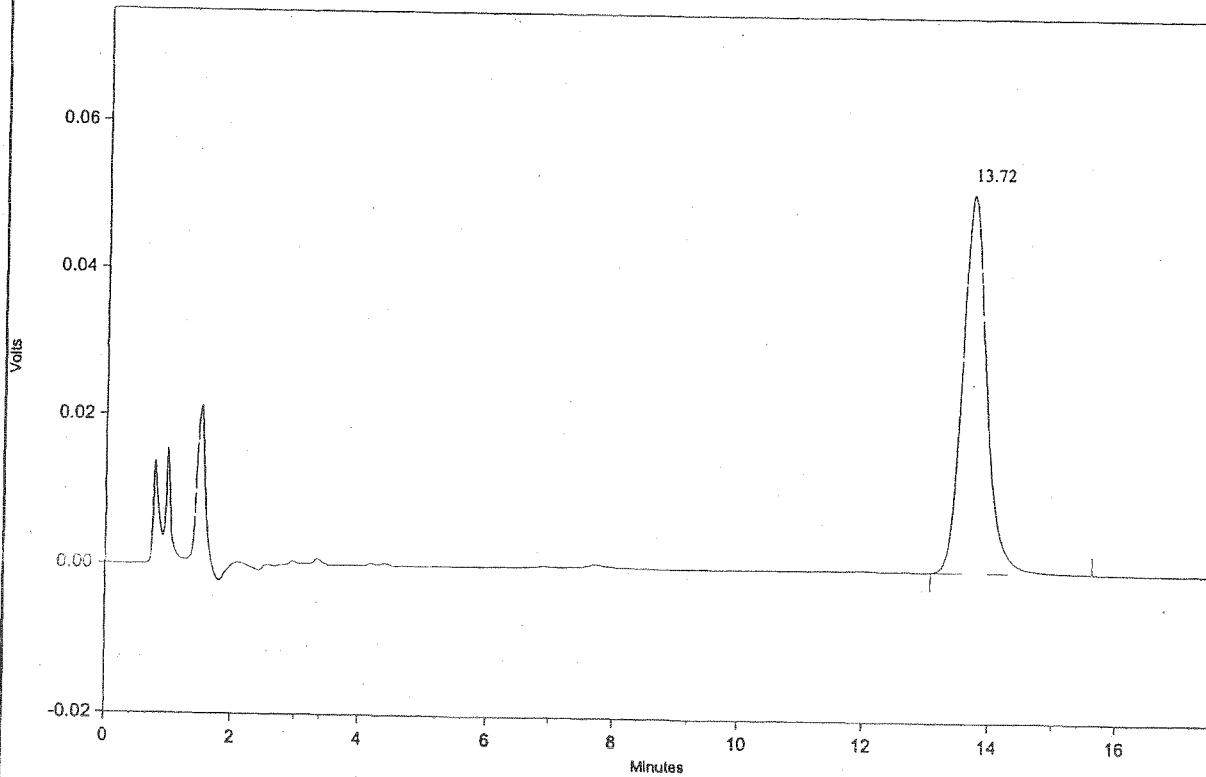
Vial: 5

Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.72	1357145	51106		1.2	0.0
Totals			1357145	51106			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 mL/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 11 of 20 pages

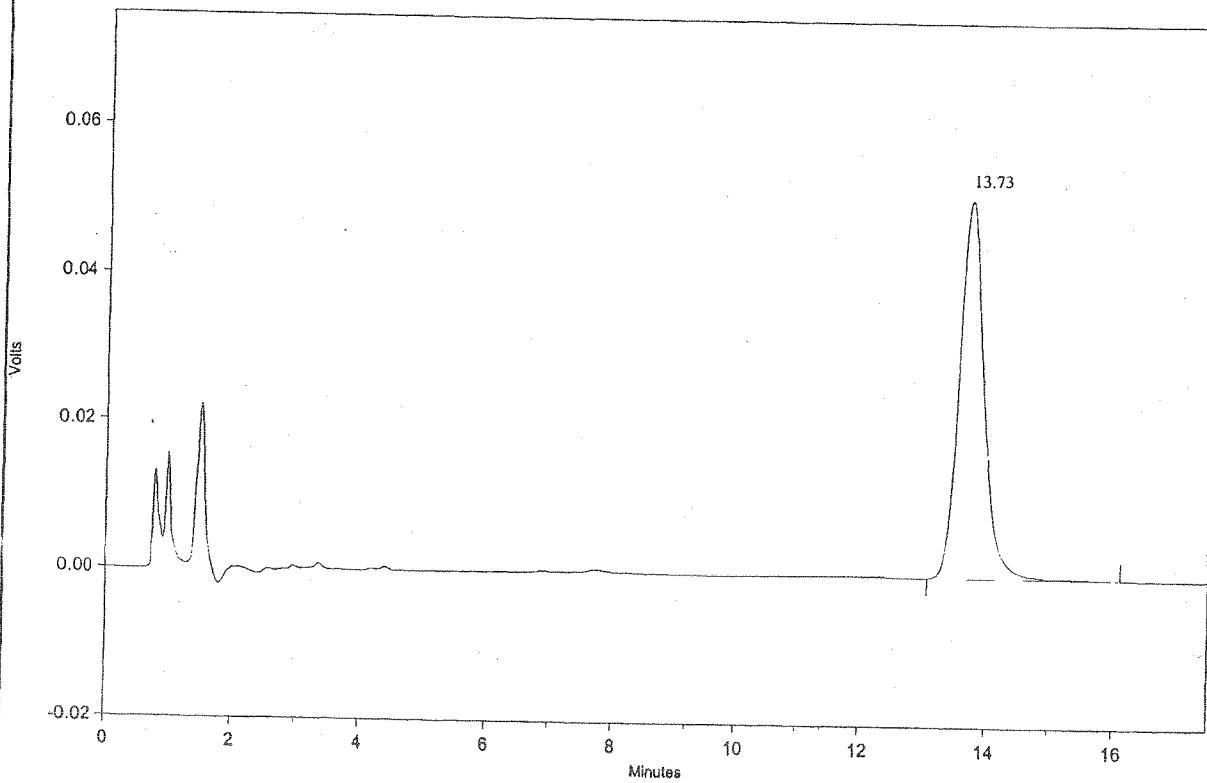
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 3
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 Date: 02/12/2008 12:01:44 PM
 Vial: 6
 Injection Volume: 50 μ l

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.73	1361144	51054		1.2	0.0
Totals			1361144	51054			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 12 of 20 pages

Product: Digoxin Tablets (0.25 mg)

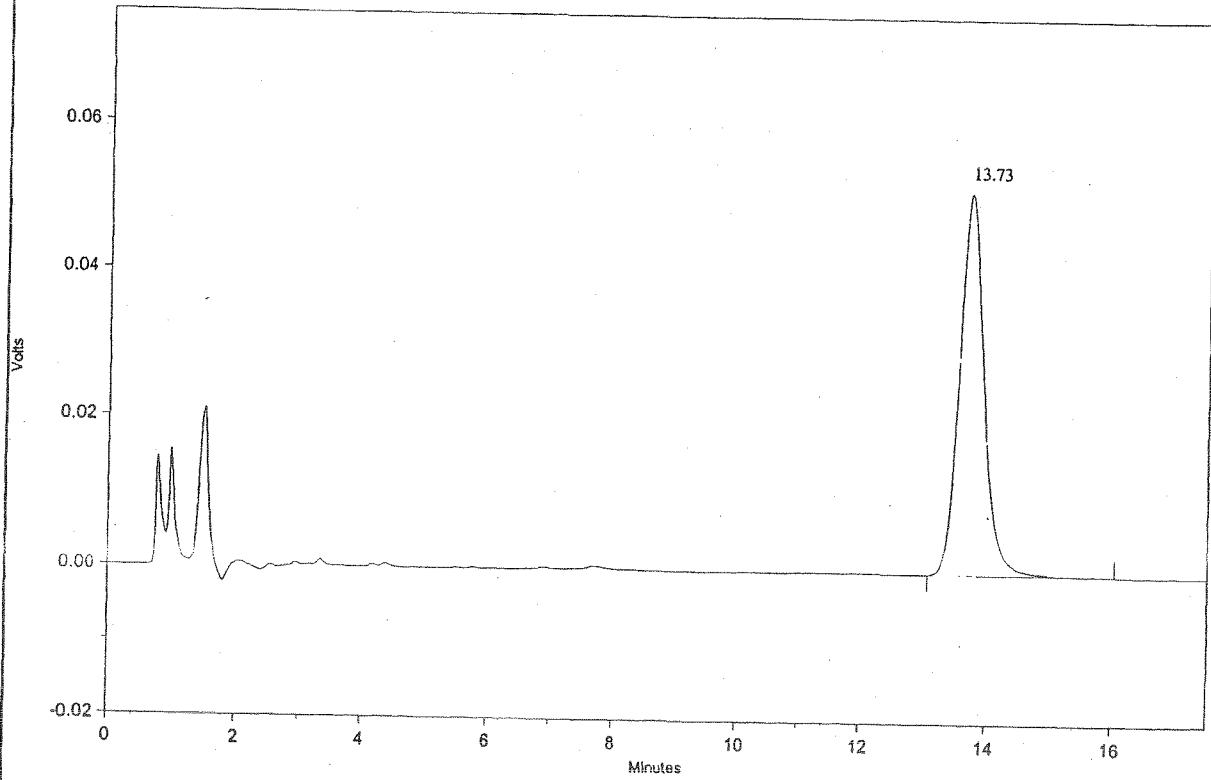
Spl.No. 448892

Name: Tablet 4
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 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab4
 Date: 02/12/2008 12:20:43 PM
 Vial: 7
 Injection Volume: 50 μ l

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.73	1375129	51481		1.2	0.0
Totals			1375129	51481			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 13 of 20 pages

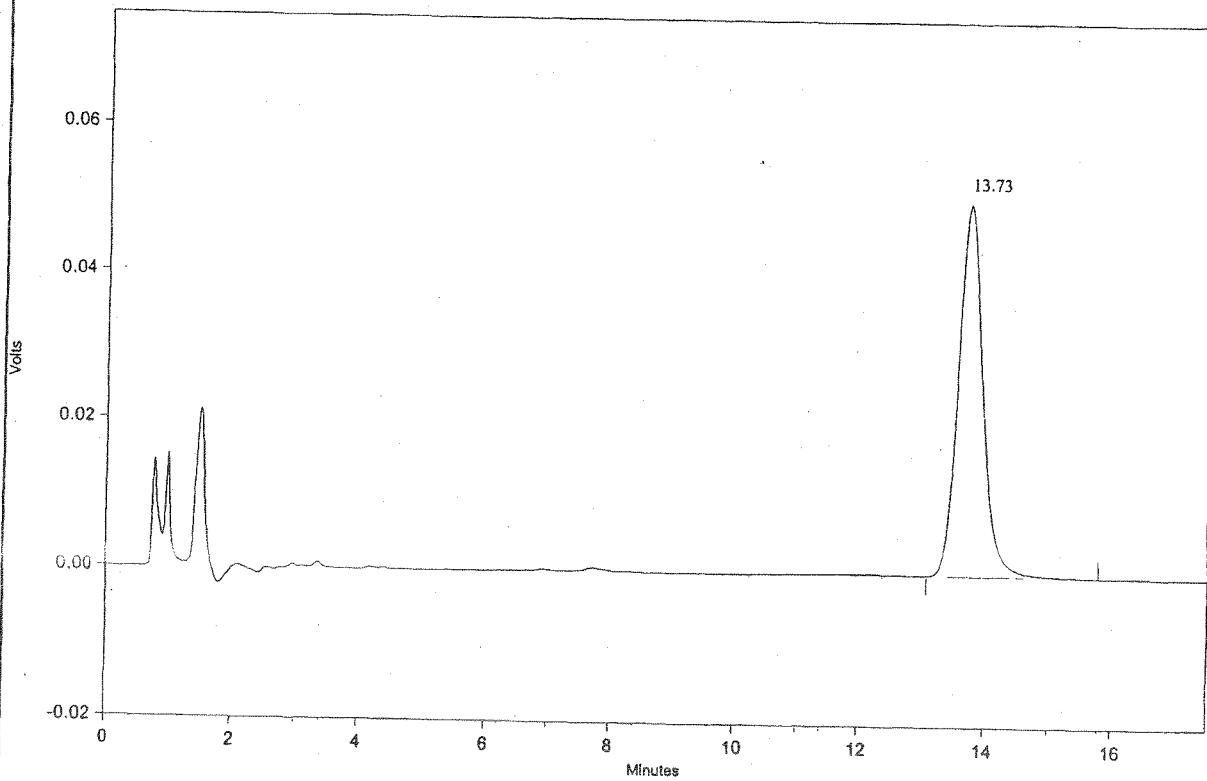
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 5
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 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab5
 Date: 02/12/2008 12:39:41 PM
 Vial: 8
 Injection Volume: 50 μ l

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.73	1333663	50208		1.2	0.0
Totals			1333663	50208			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 14 of 20 pages

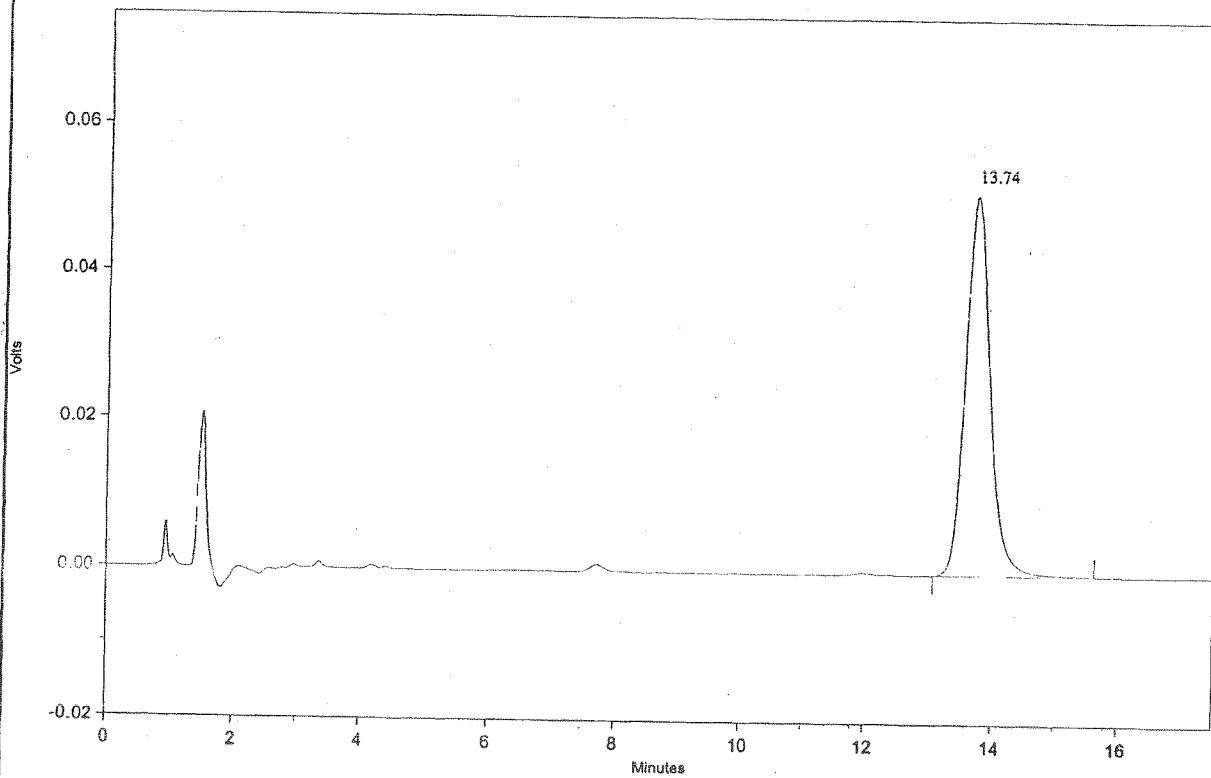
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)
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 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln.6
 Date: 02/12/2008 12:58:40 PM
 Vial: 2
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.74	1360111	51218		1.2	0.0
Totals			1360111	51218			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 mL/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 15 of 20 pages

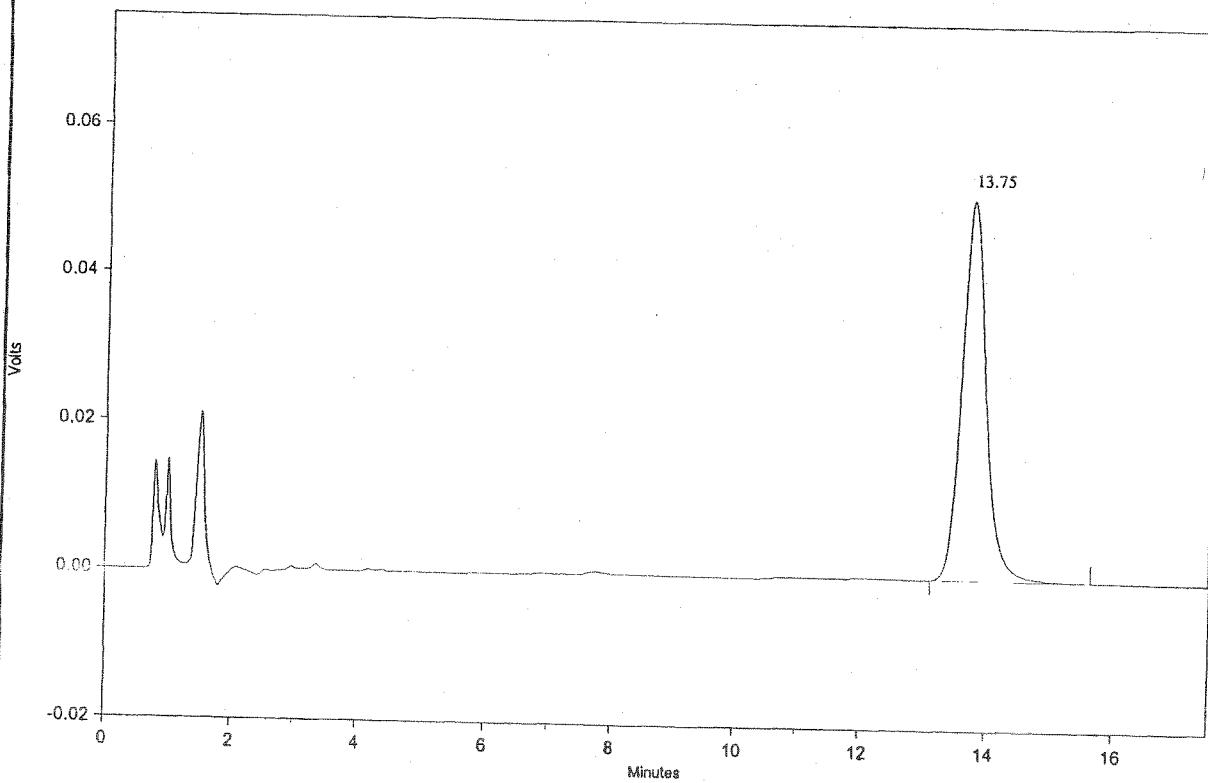
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 6
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 File: C:\CLASS-VP\DATA\DigoxinTabs448892\Tab6
 Date: 02/12/2008 1:18:49 PM
 Vial: 9
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.75	1366084	51225		1.2	0.0
Totals			1366084	51225			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 mL/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 16 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 7

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab7

Date: 02/12/2008 1:37:47 PM

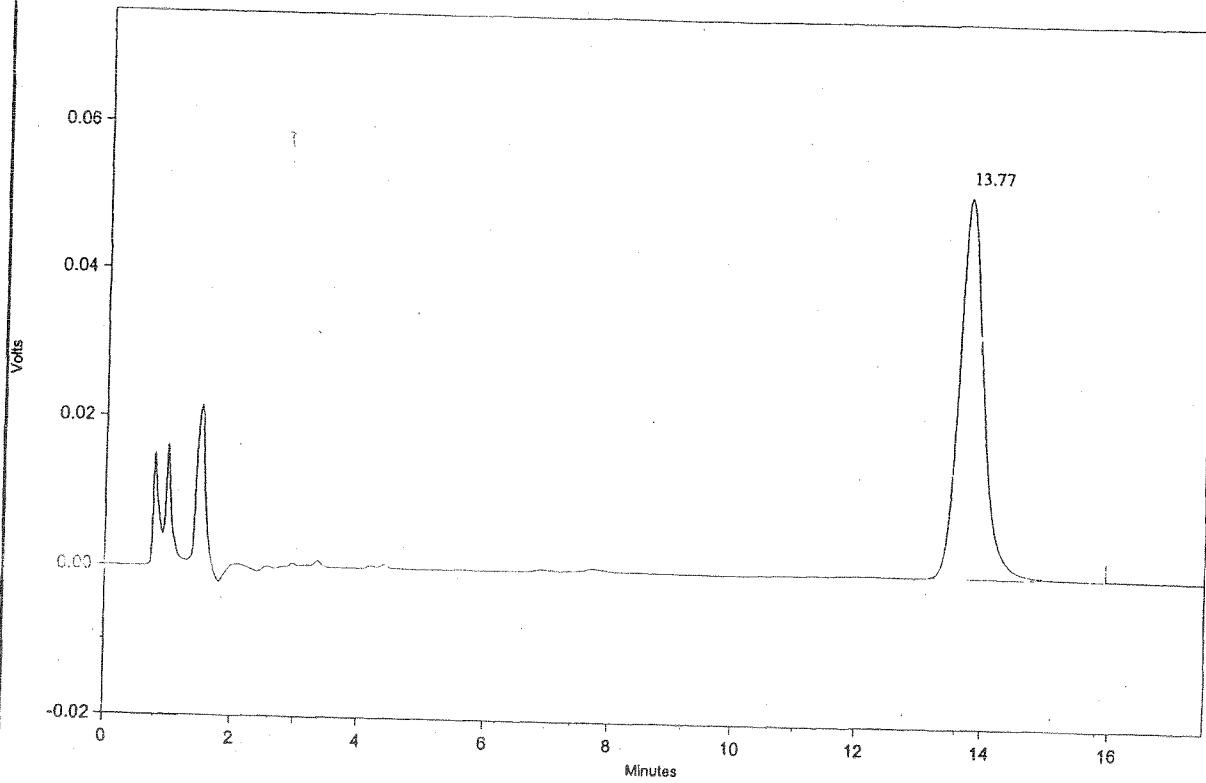
Vial: 10

Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.77	1377397	51362		1.2	0.0
Totals			1377397	51362			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 17 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 8

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab8

Date: 02/12/2008 1:58:03 PM

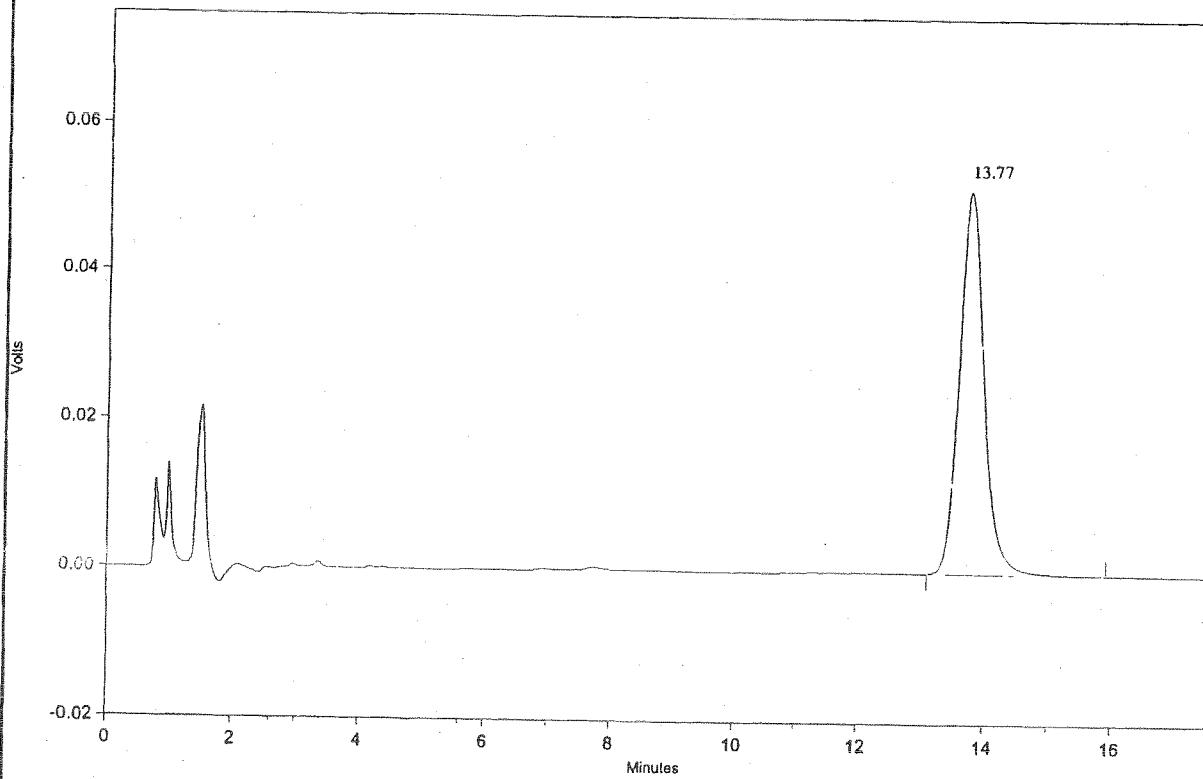
Vial: 11

Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.77	1375557	51662		1.2	0.0
Totals			1375557	51662			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 18 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 9

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab9

Date: 02/12/2008 2:17:02 PM

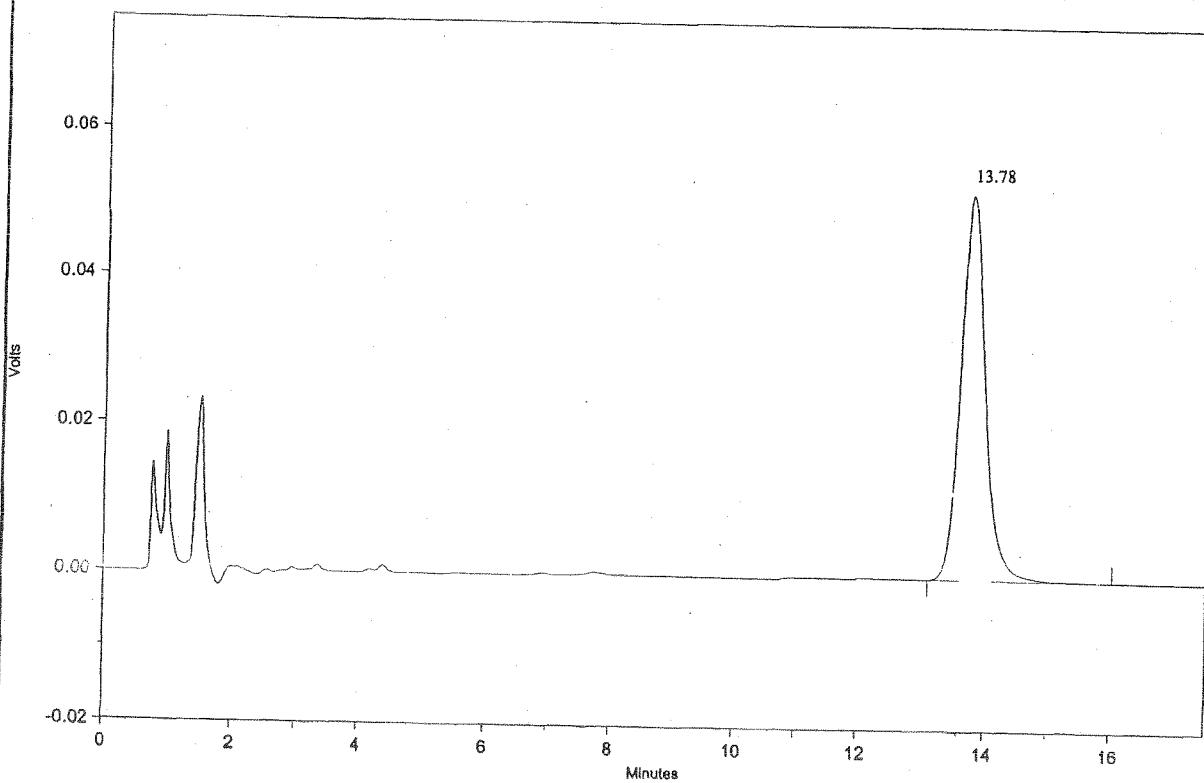
Vial: 12

Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.78	1389731	51926		1.2	0.0
Totals			1389731	51926			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 19 of 20 pages

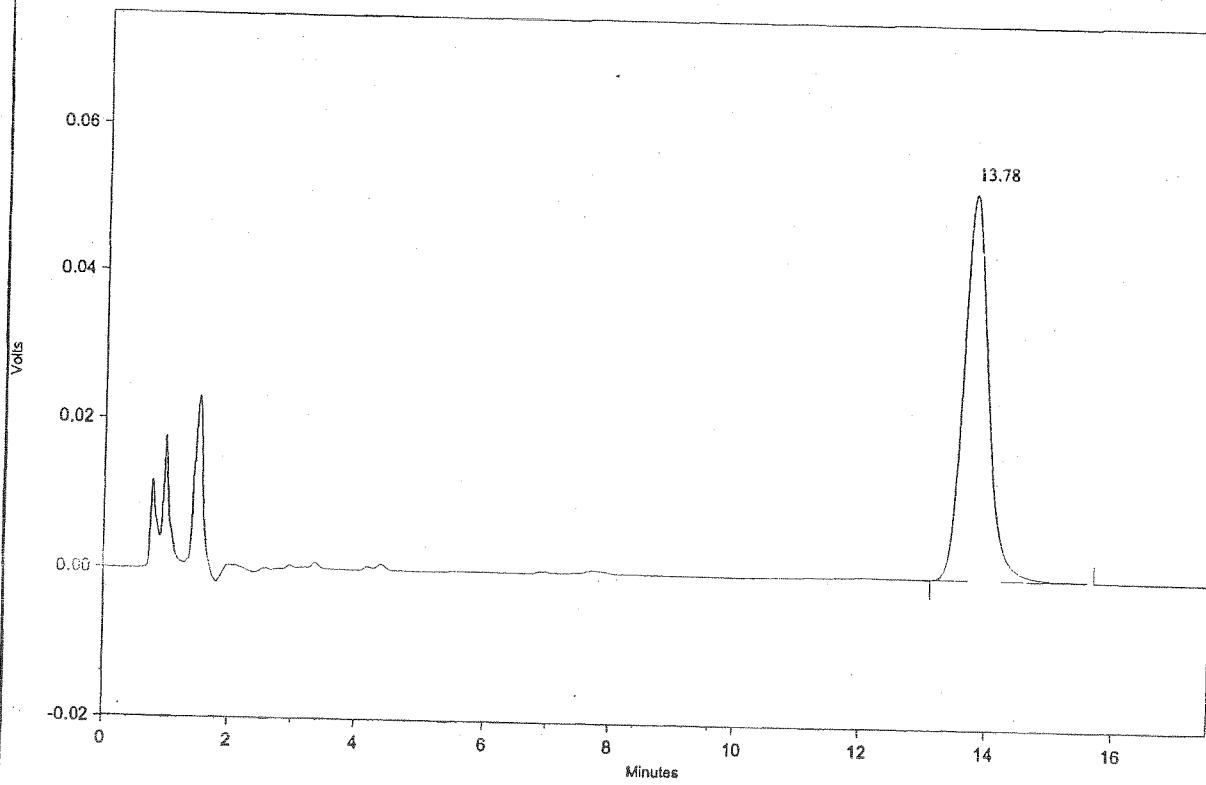
Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 10
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab10
 Date: 02/12/2008 2:36:00 PM
 Vial: 13
 Injection Volume: 50 ul

Detector A
 (218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.78	1394609	52172		1.2	0.0
Totals			1394609	52172			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)
 Analyst: Valentino Fiorella
 Mobile Phase: Acetonitrile/Water (26/74)
 Flow: 2.0 ml/min.
 Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 20 of 20 pages

Product: Digoxin Tablets (0.25 mg)

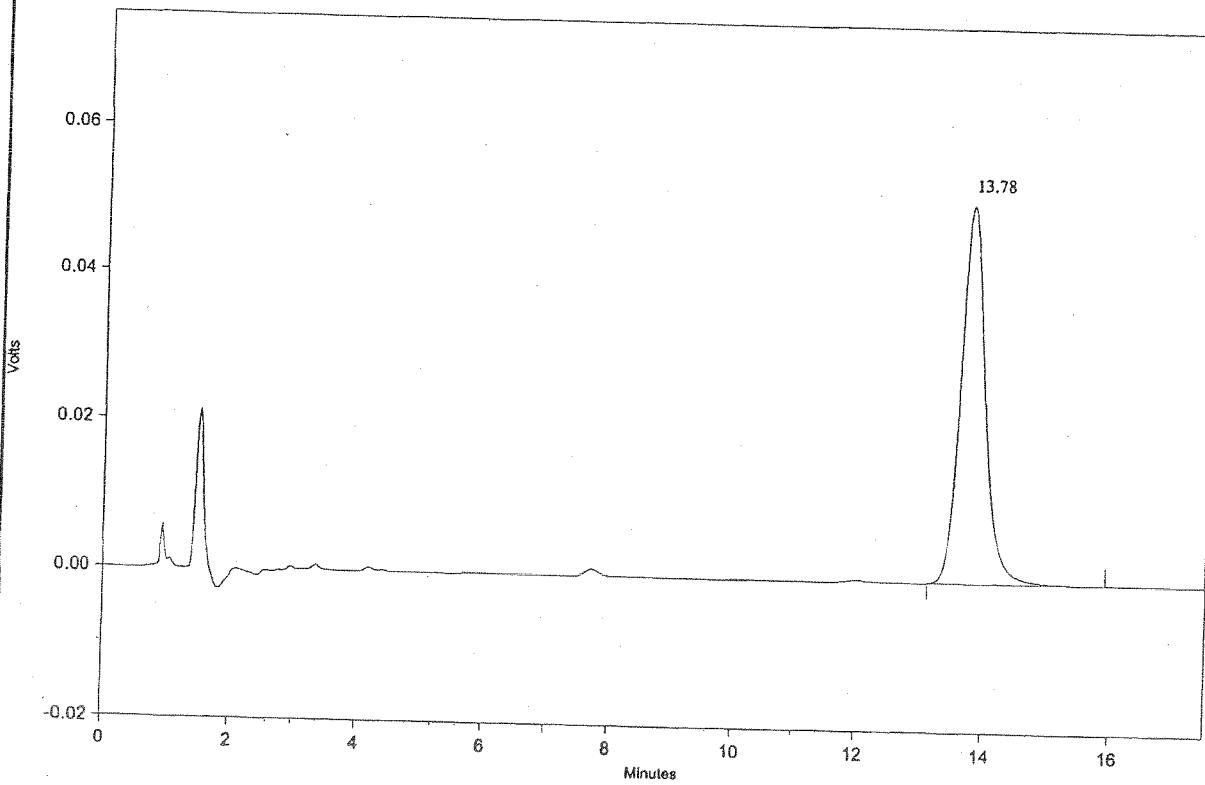
Spl.No. 448892

Name: Standard Solution 1 (CCV)
 Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
 File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln.7
 Date: 02/12/2008 2:54:53 PM
 Vial: 2
 Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.78	1363877	51047		1.2	0.0
Totals			1363877	51047			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

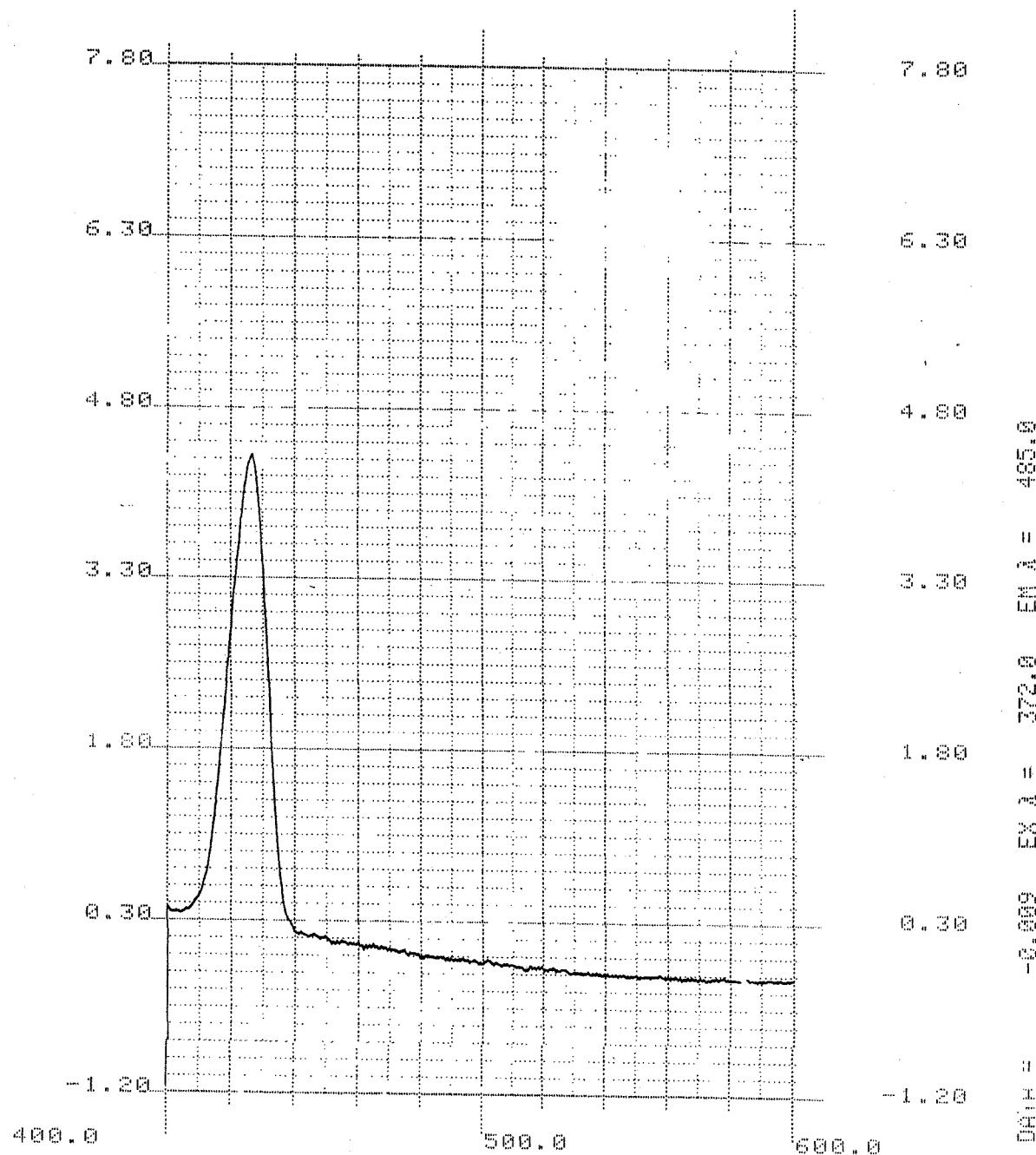
Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

Attachment B

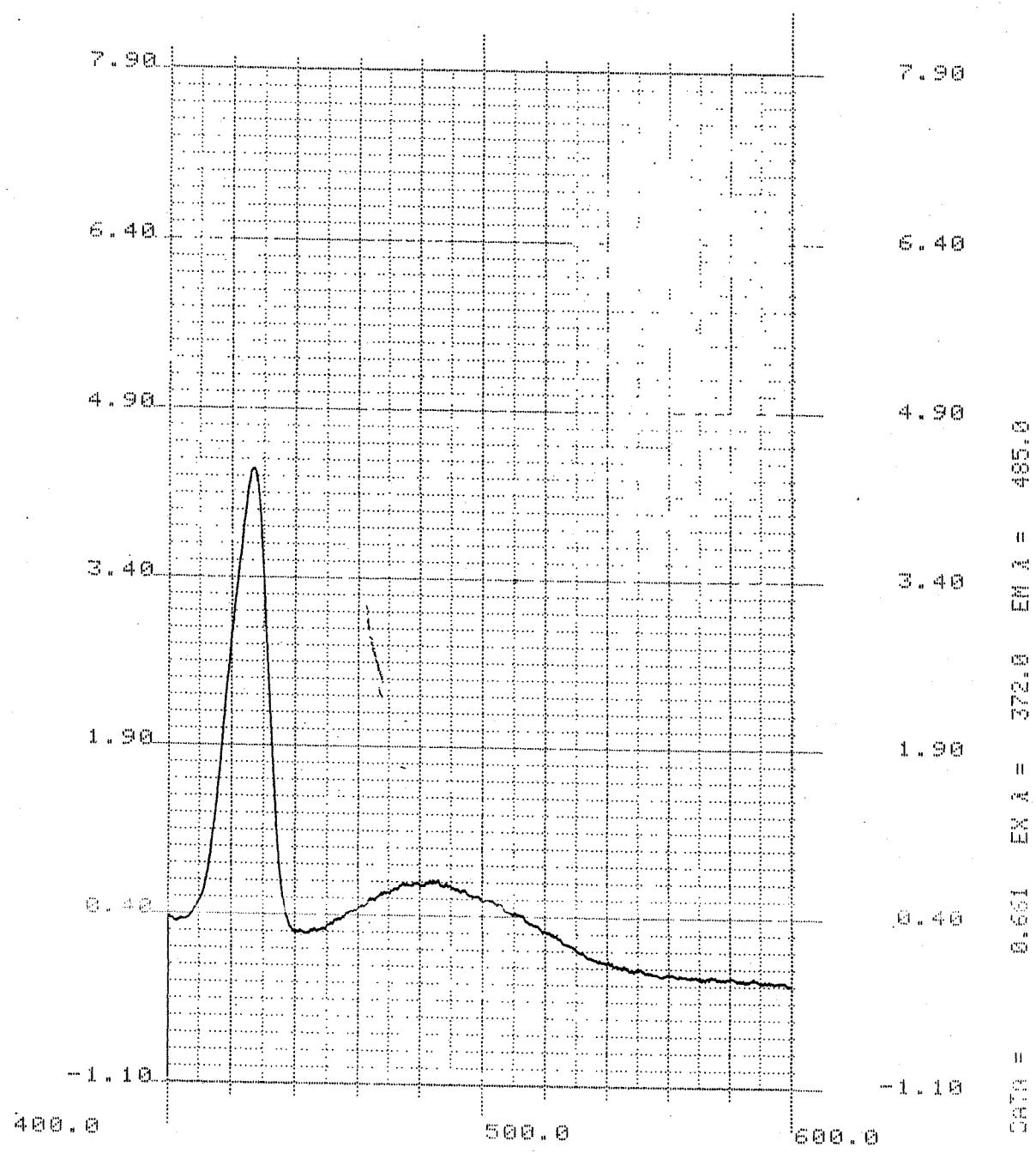
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08

Spl# 448892
4/25/08 D2b

Blank

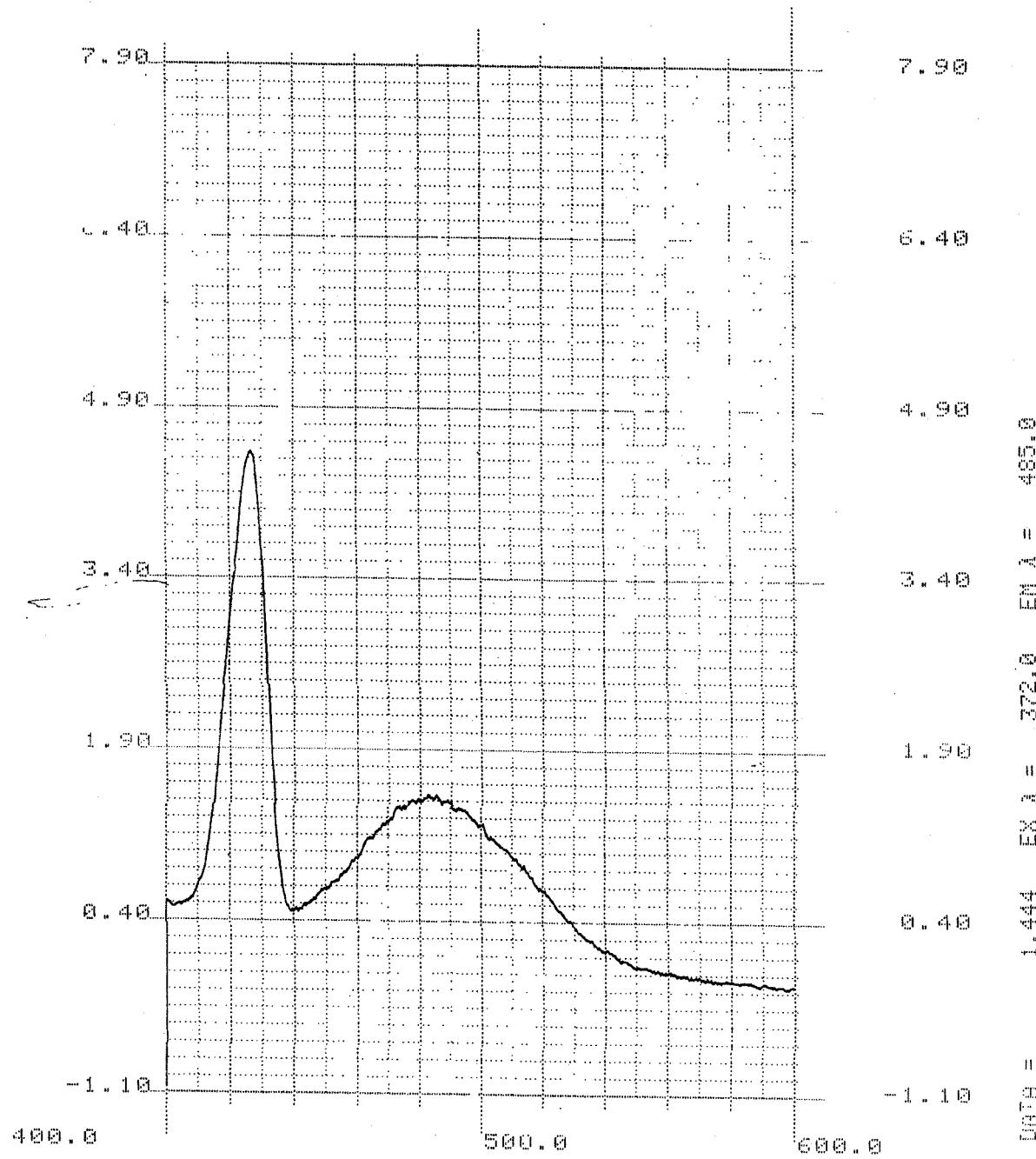


Attachment B

Digoxin Tablets (0.25 mg)

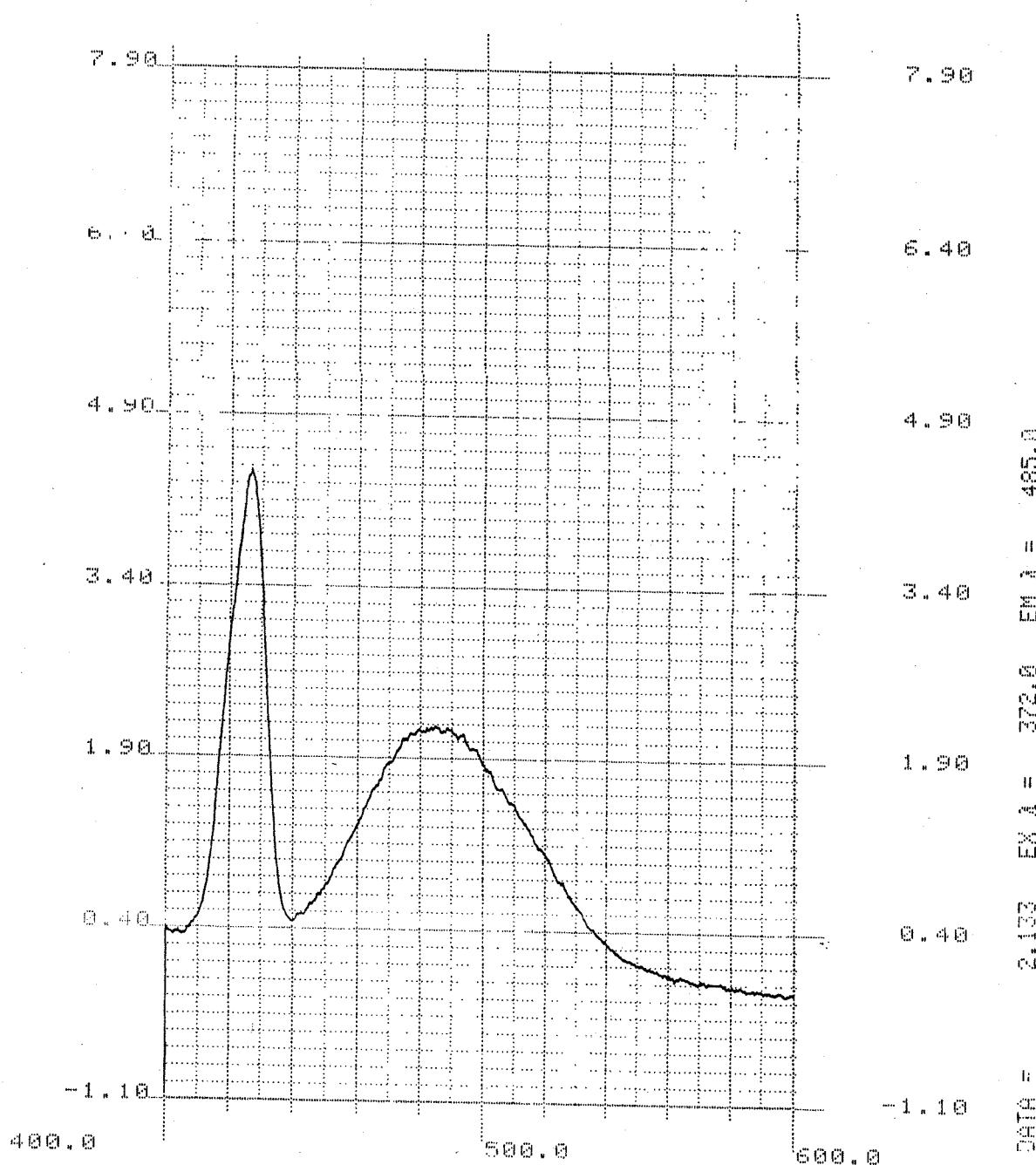
Spl.# 448892

4/25/08



⊕ SHIMADZU CORPORATION CHART 200-91527

40%



std 60%

SHIMADZU CORPORATION CHART 200-91527

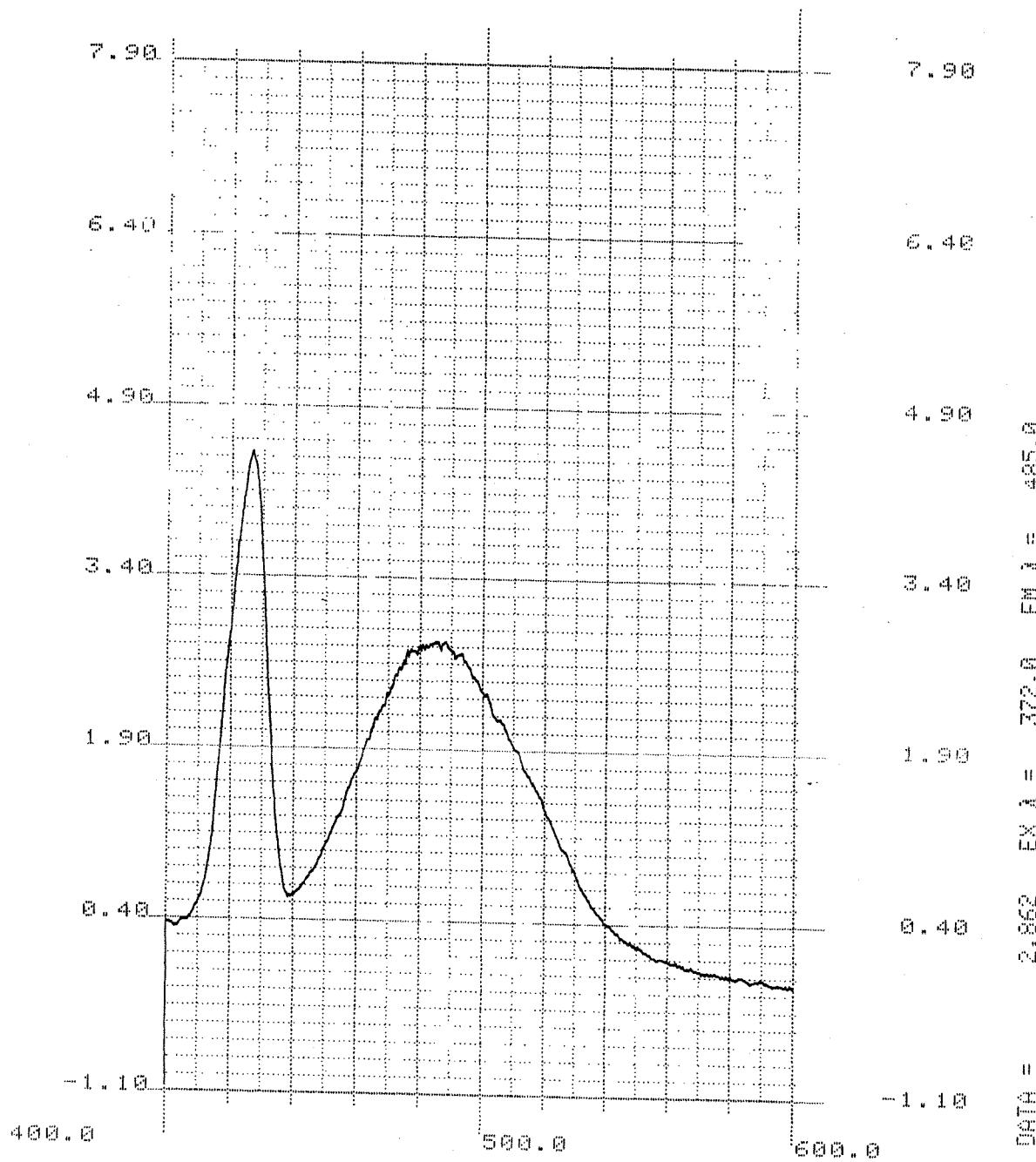
60%

Attachment B

Digoxin Tablets (0.25 mg)

Spl.# 448892

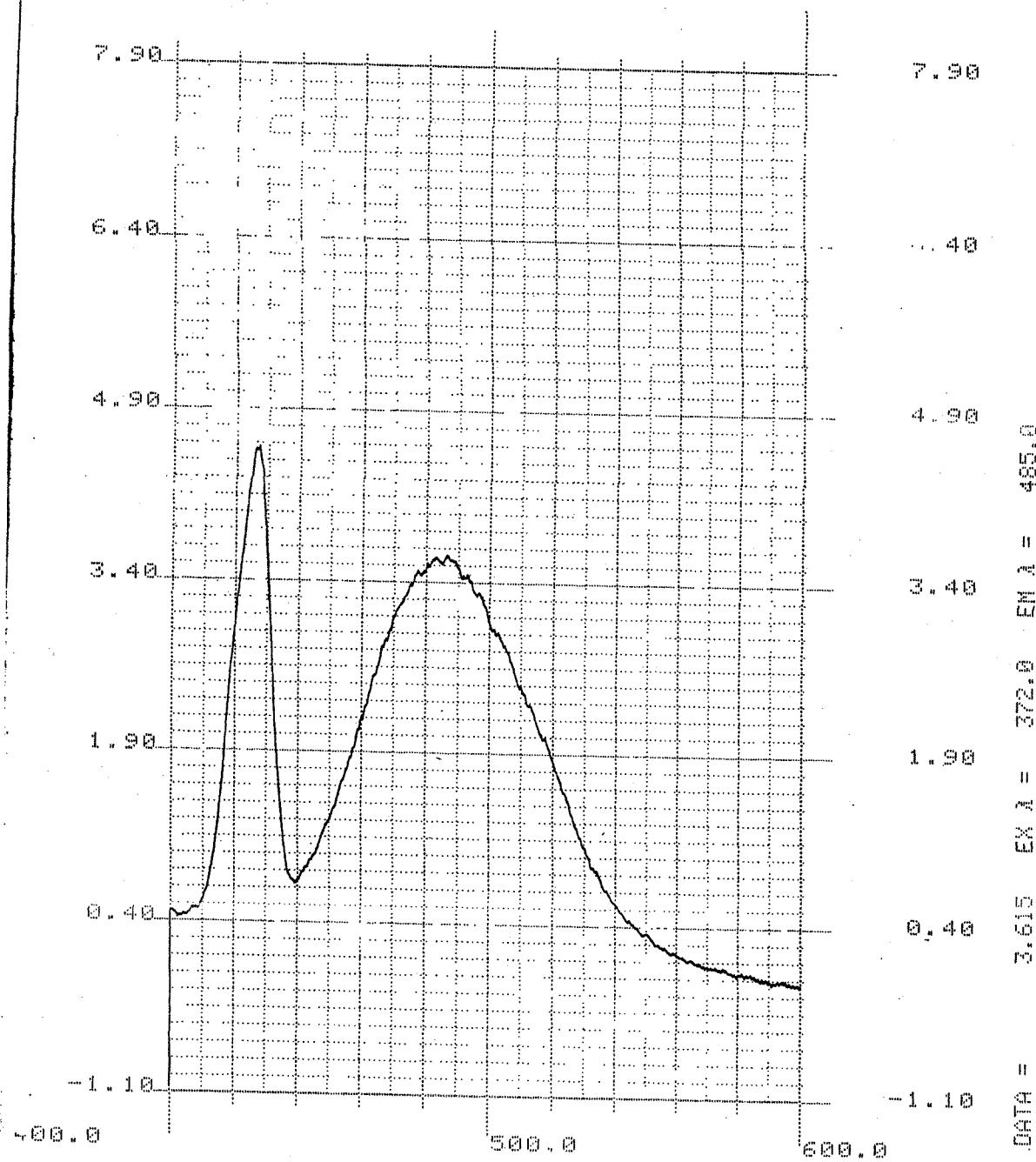
4/25/08



Std 80%

⊕ SHIMADZU CORPORATION CHART 200-91527

80%



std 100%

⊕ SHIMADZU CORPORATION CHART 200-91527

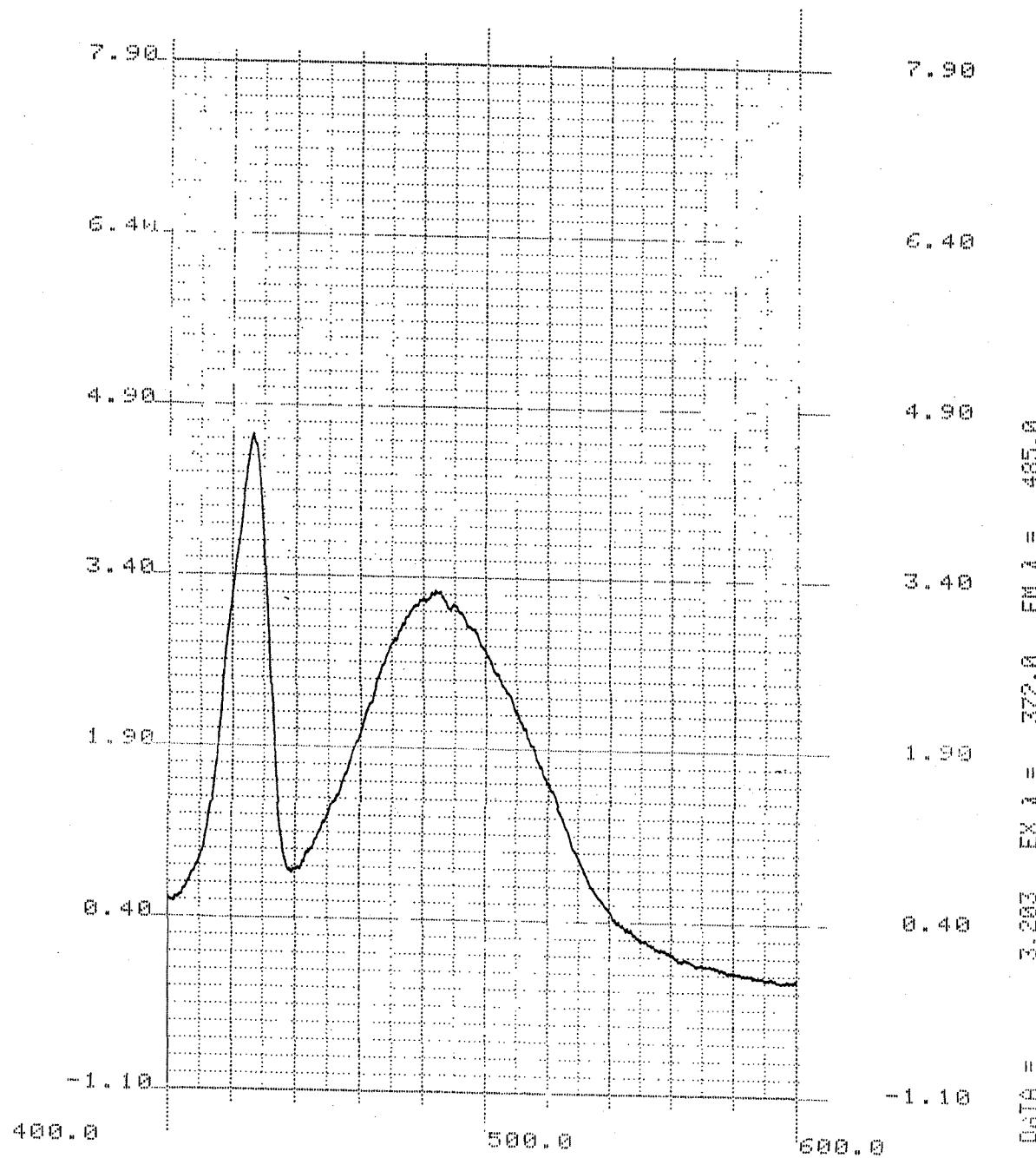
100%

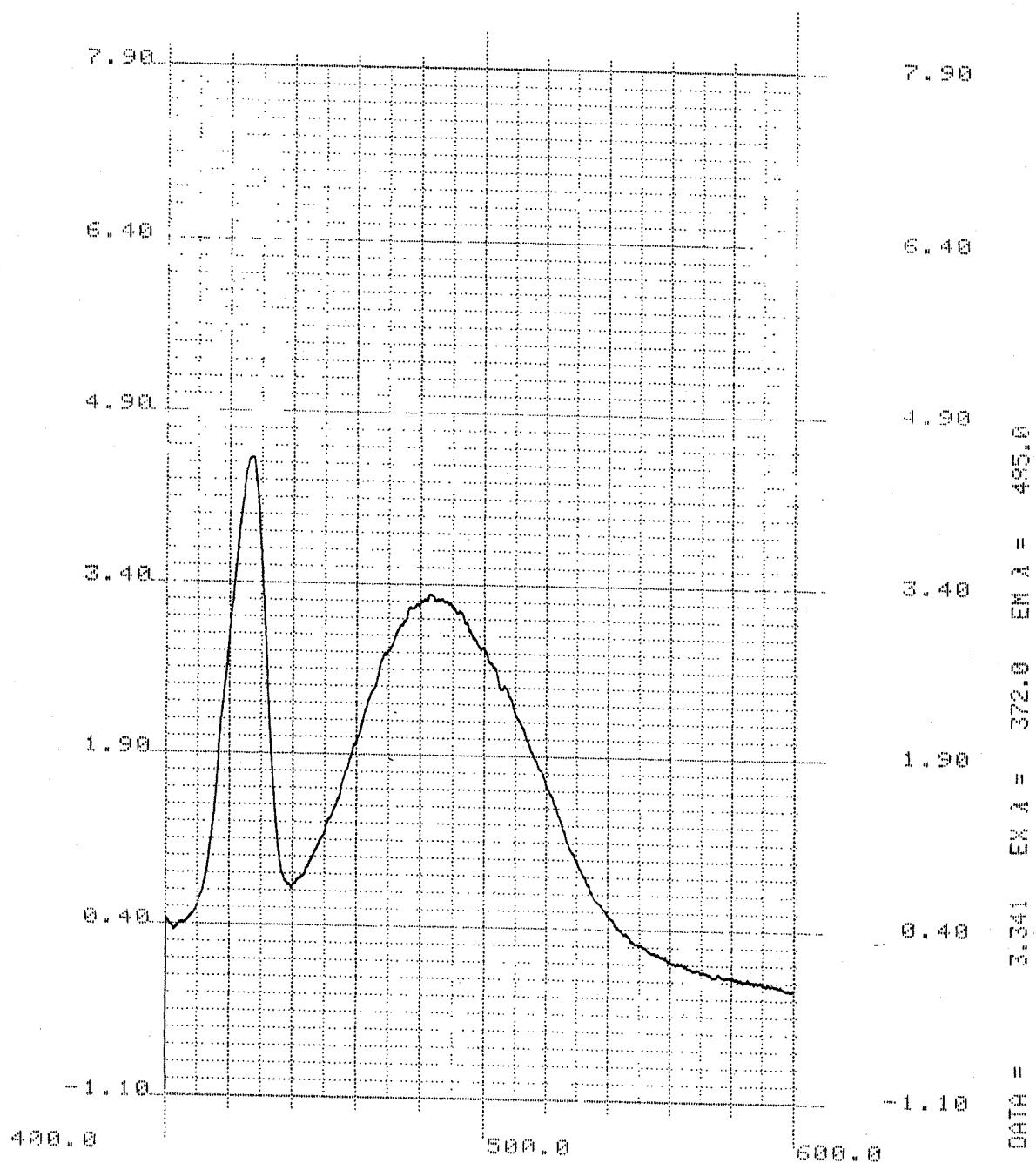
Attachment B

Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08





Tab 1-2

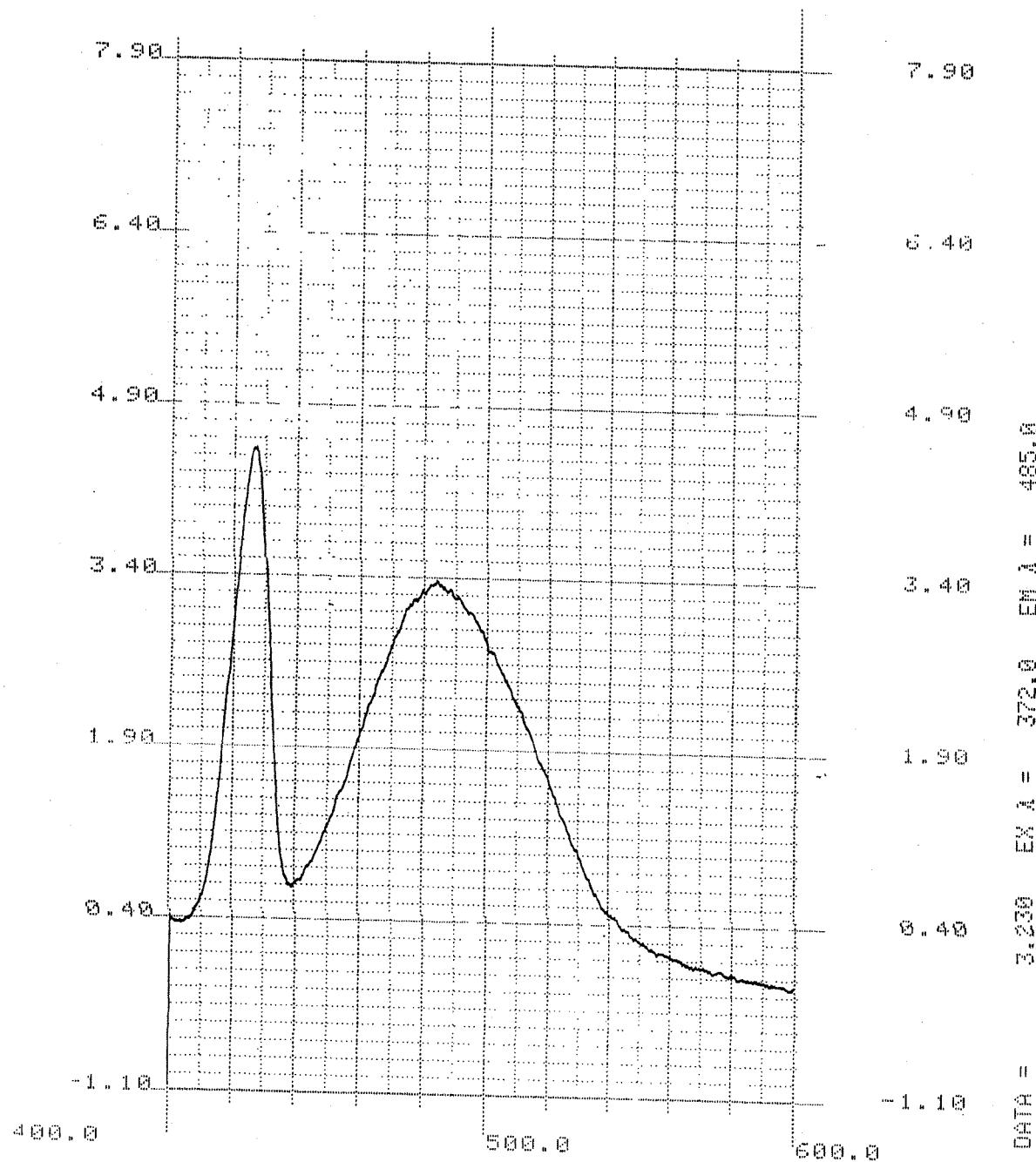
SHIMADZU CORPORATION CHART 200-91527

Attachment B

Digoxin Tablets (0.25 mg)

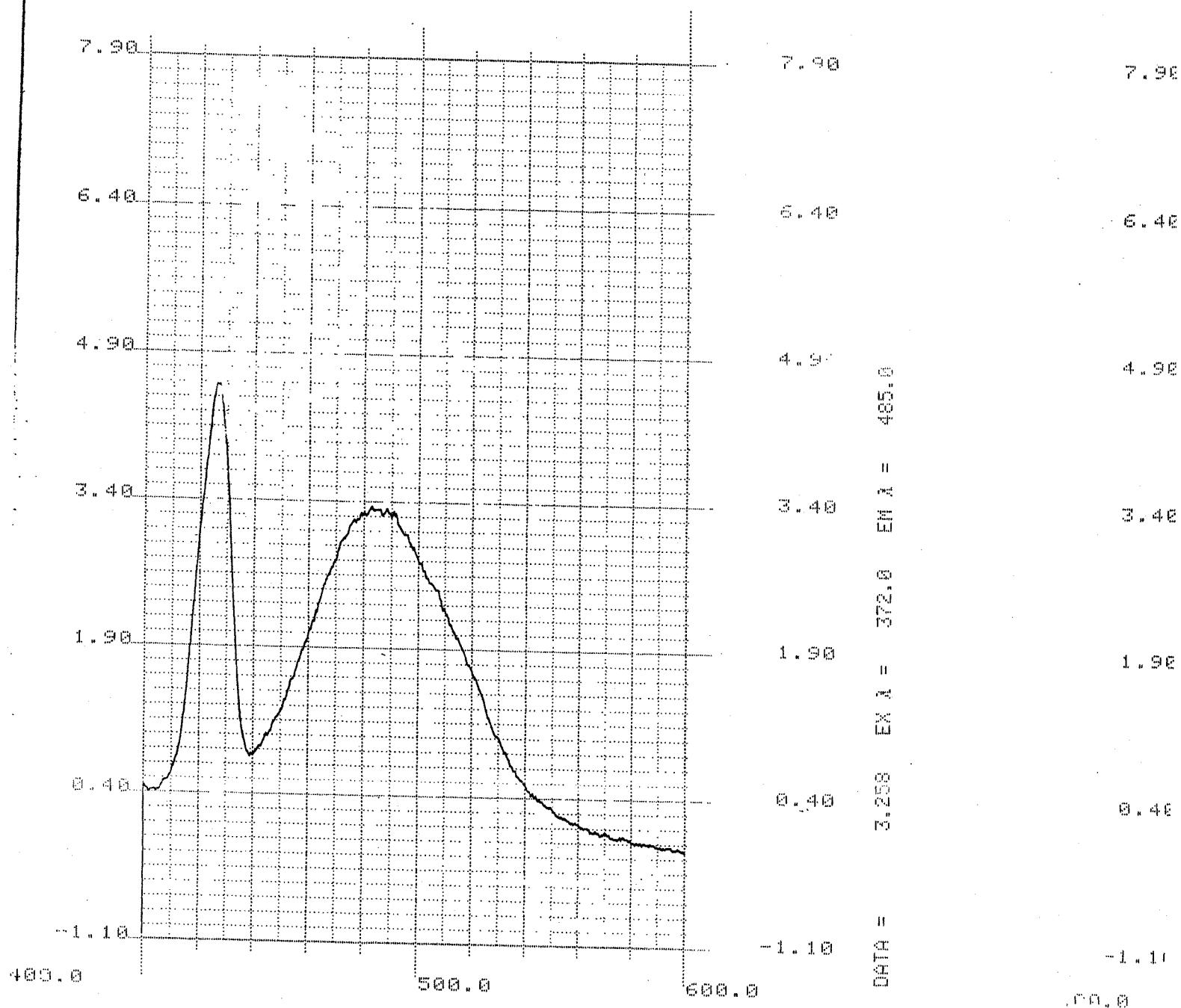
Spl.# 448892

4/25/08



Tab 2 - 1

⊕ SHIMADZU CORPORATION CHART 200-91527



Tab 2-2

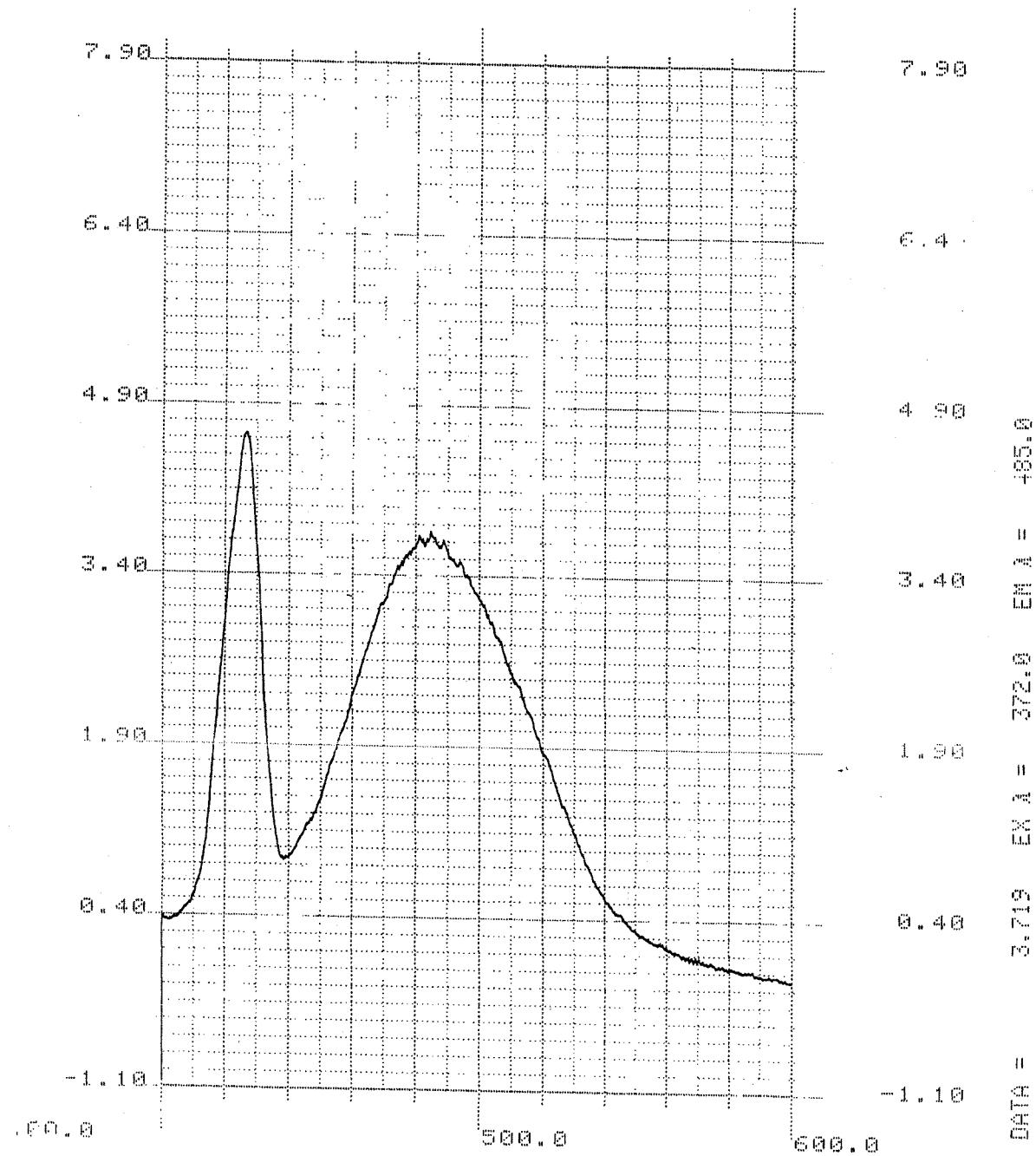
⊕ SHIMADZU CORPORATION CHART 200-91527

Attachment B

Digoxin Tablets (0.25 mg)

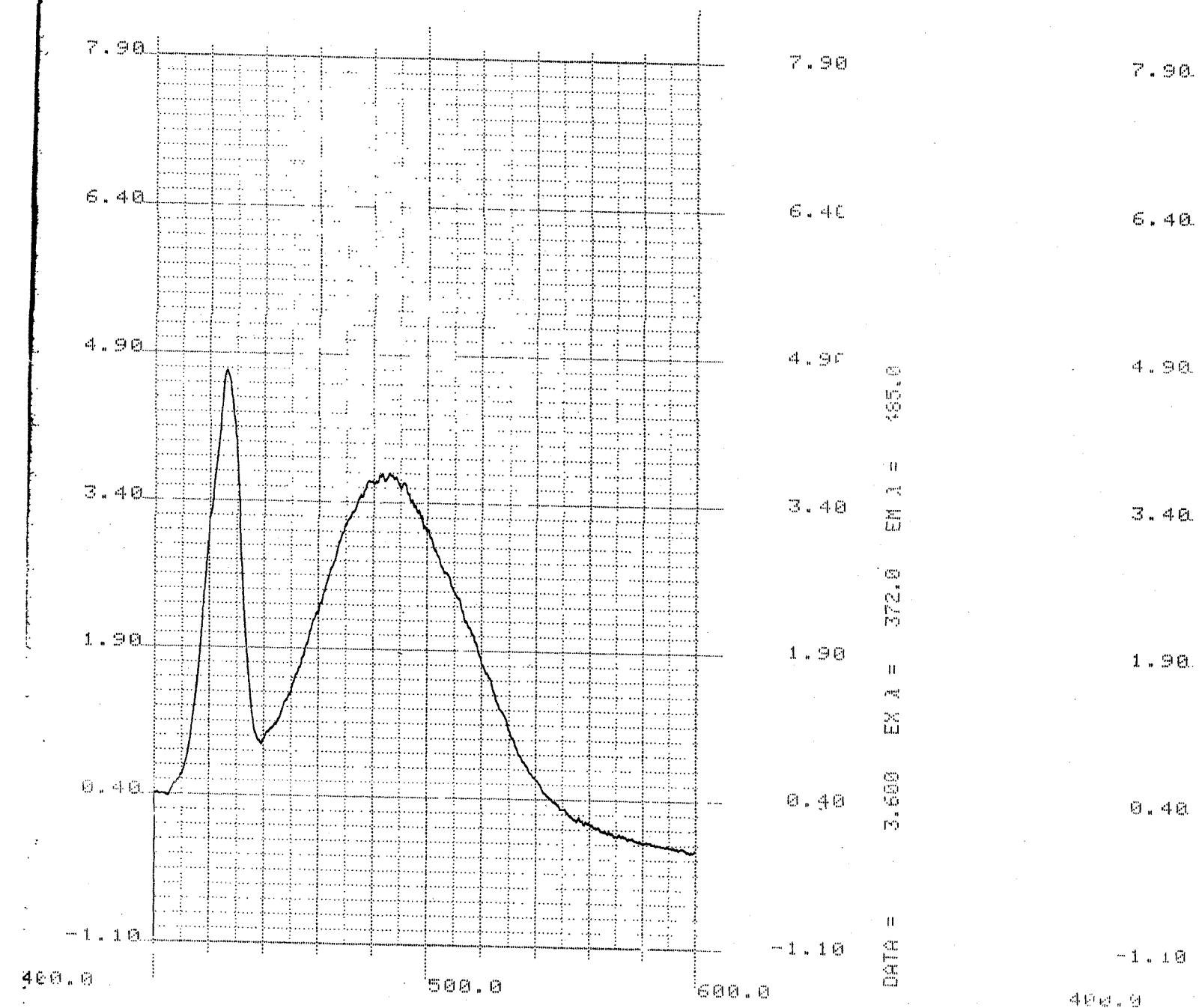
Sp1.# 448892

4/25/08



Tab 3-1

⊕ SHIMADZU CORPORATION CHART 200-91527



Tab 3-2

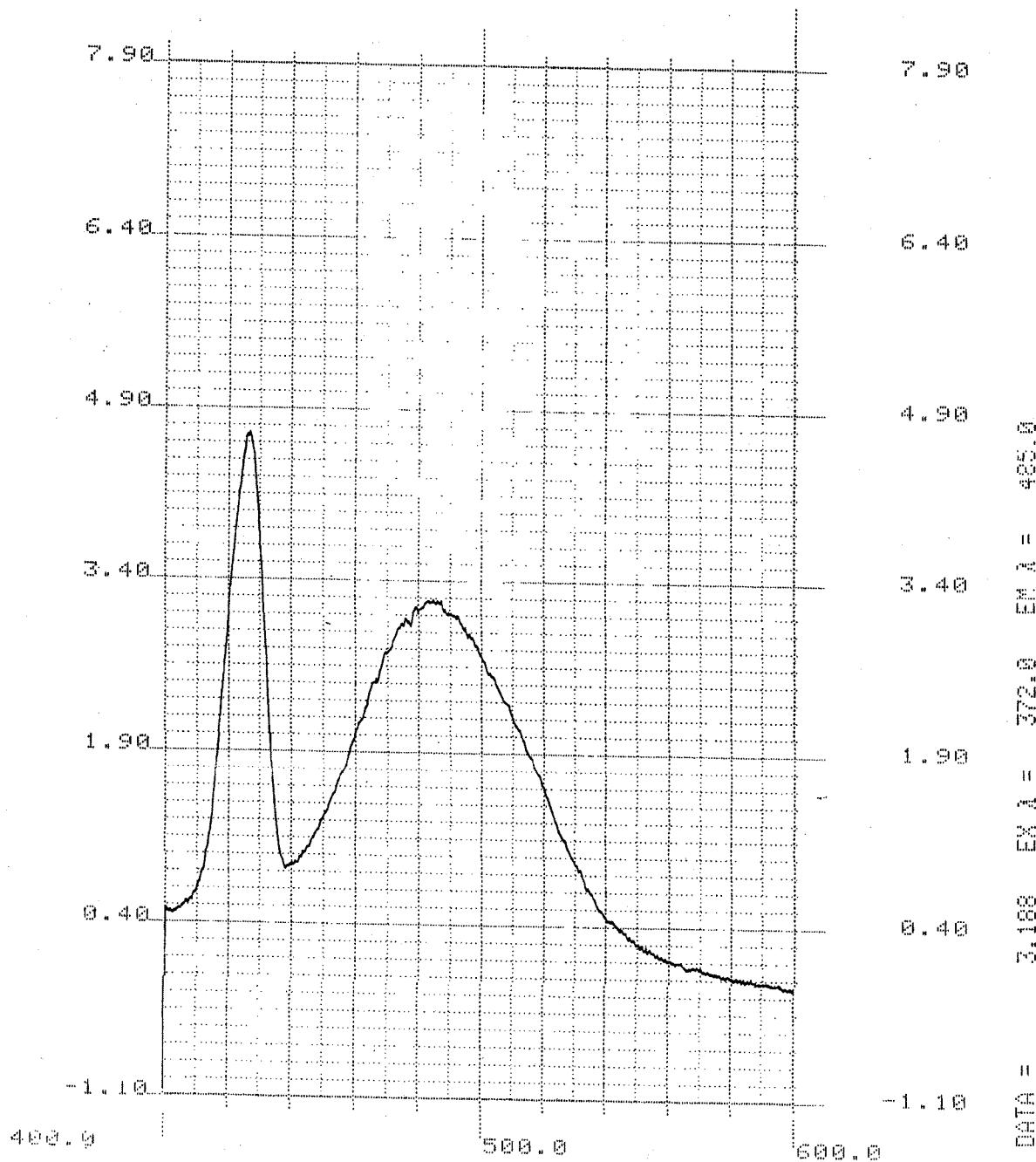
⊕ SHIMADZU CORPORATION CHART 200-91527

Attachment B

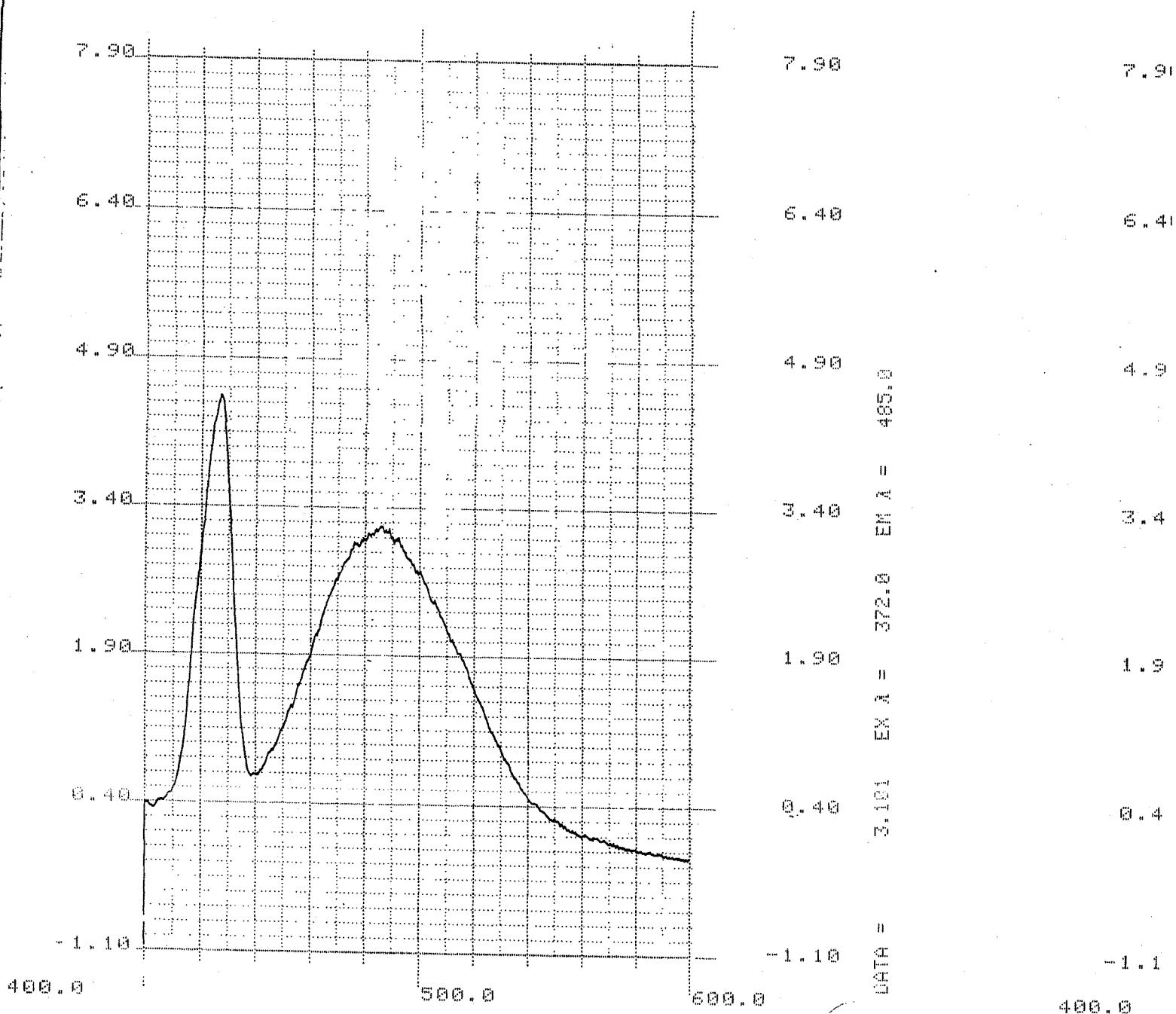
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08



Tab 4-1



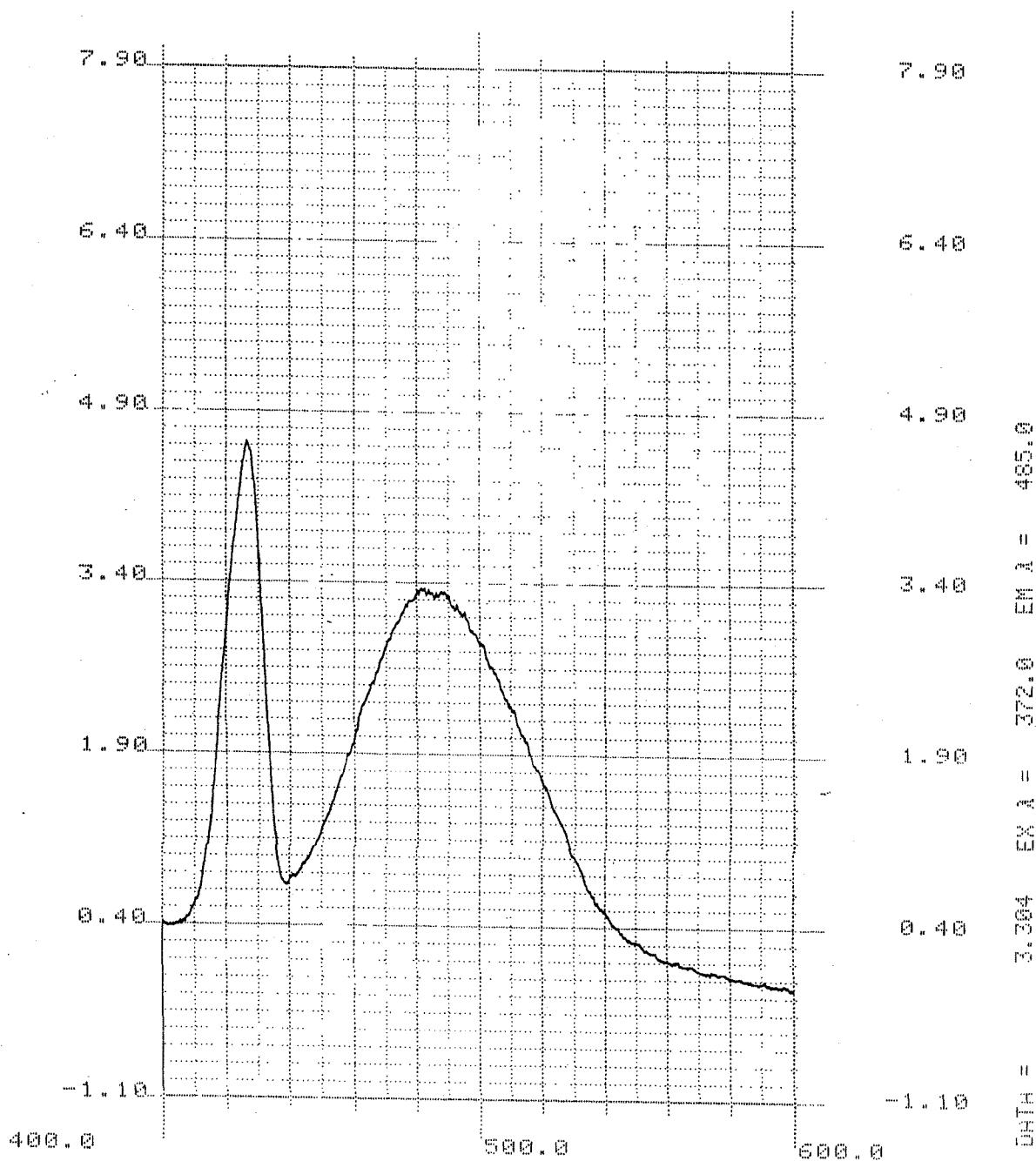
SHIMADZU CORPORATION CHART 200-91527

Attachment B

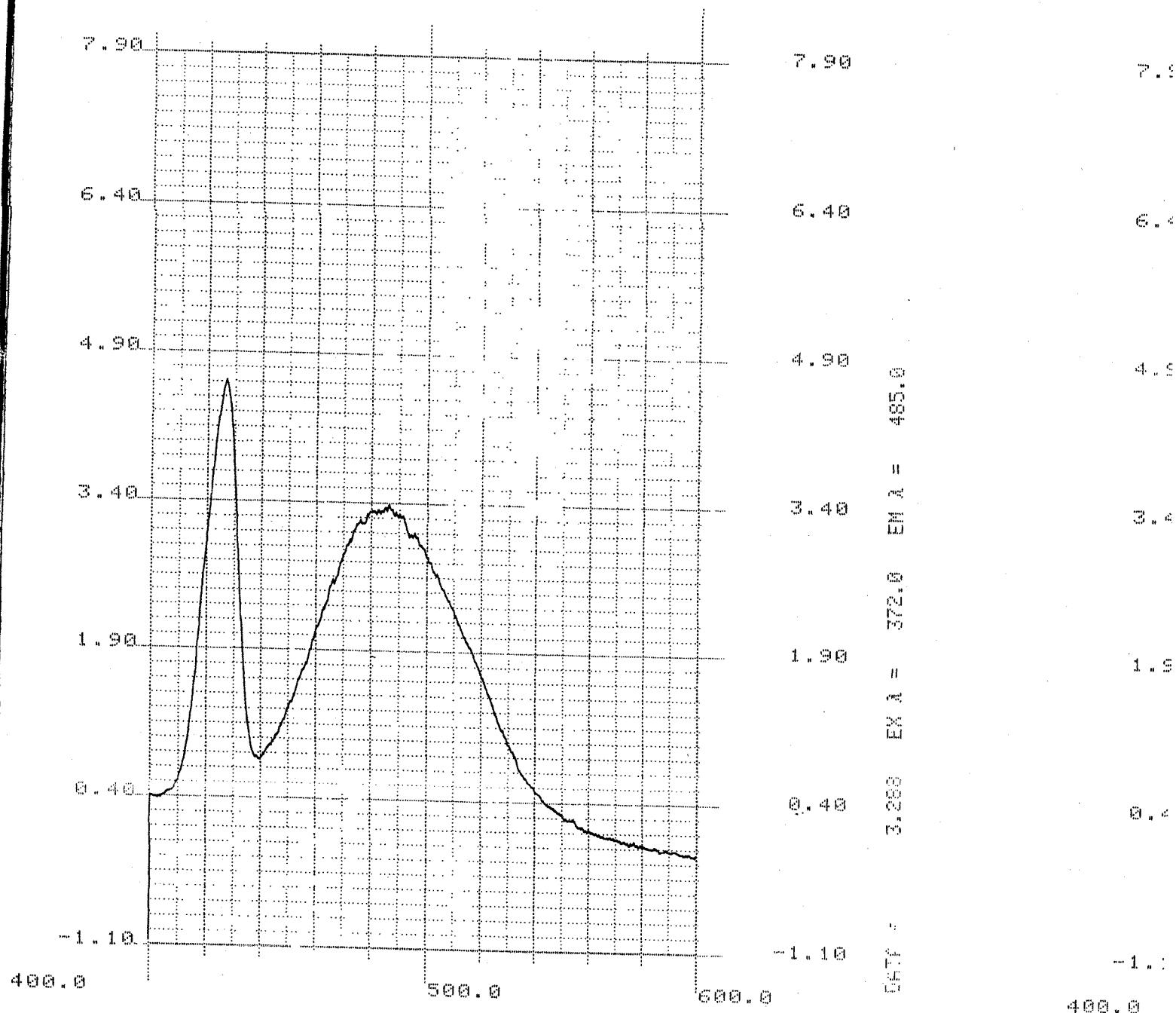
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08



Tab 5-1



tab 5-2

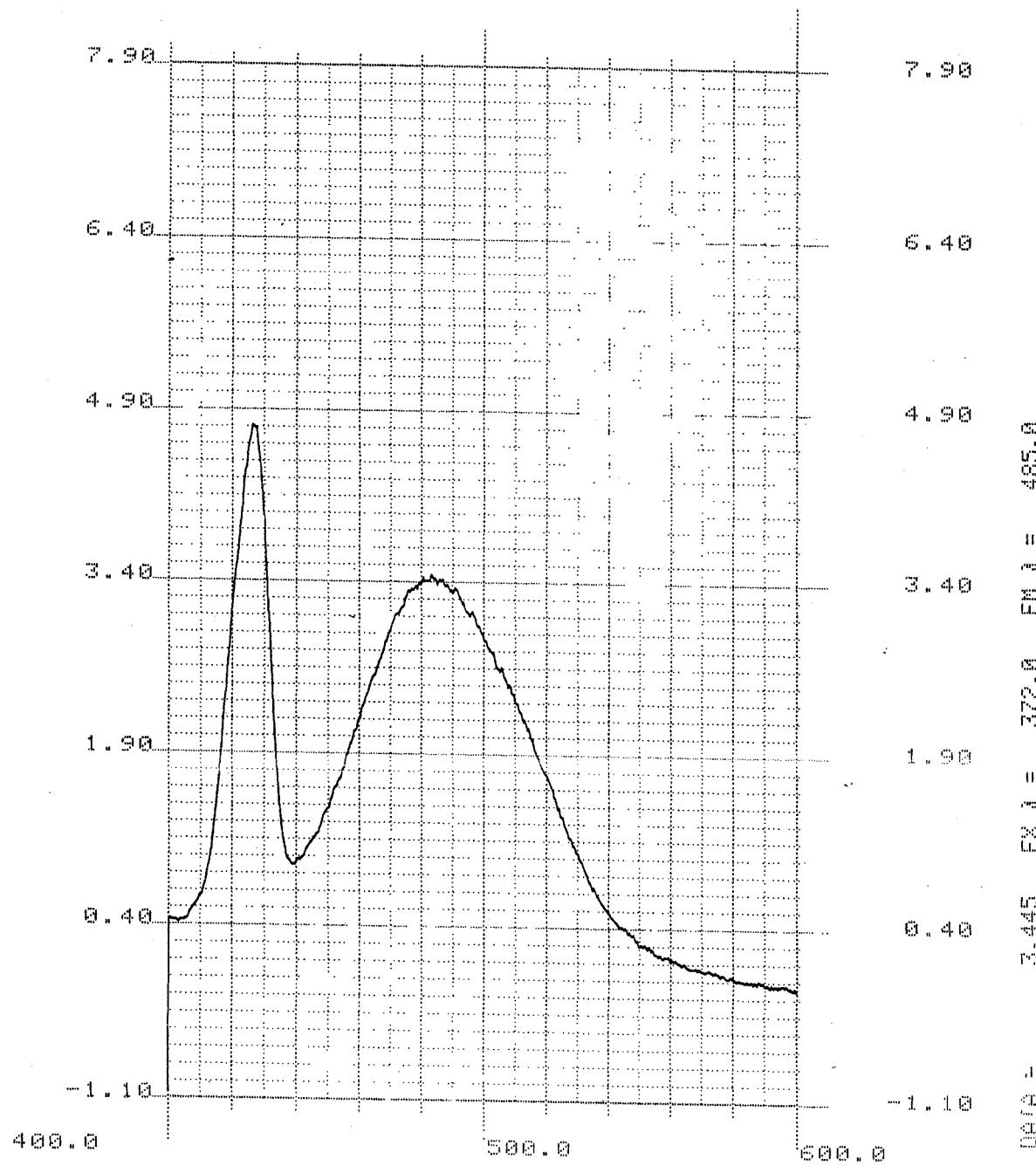
SHIMADZU CORPORATION CHART 200-91527

Attachment B

Digoxin Tablets (0.25 mg)

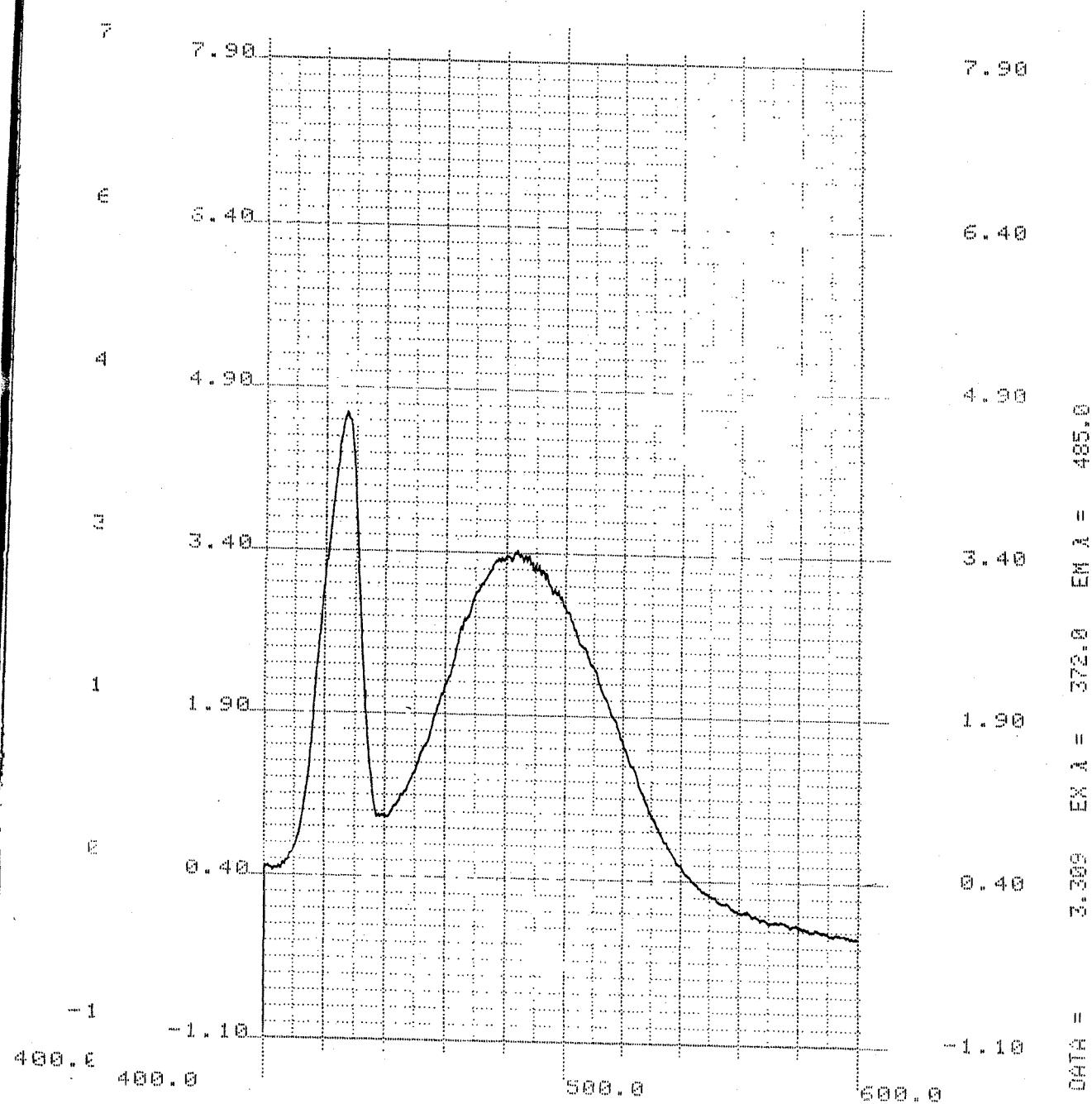
Spl.# 448892

4/25/08



Tab 6-1

SHIMADZU CORPORATION CHART 200-91527



Tab 6-2

⊕ SHIMADZU CORPORATION CHART 2

Flag	Flag Remarks				
Survey Sample	FY 2008 Low Cost Generic Drug Sample Survey # 2008-800				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Surveillance	Official	0882662	Completed
FEI 1610608	Date Collected 12/03/2007	Product Code 63FCA06	Responsible Firm Shipper	PAC 56008A	Hours 2
Compliance Num	Country of Origin United States				
Related Smpl Num	Position Class INV	Sampling District DET-DO	NDC Number 62794-146-01	Permit Number	Storage Rqrmnt. Ambient
Dealer is Consumer No	Crx/DEA Schedule	Recall Num	Consumer Compl. Num Digitek	Brand Name	

Product Description

100 x 0.25mg Digoxin Tablets, USP

Product Label

See continuation.

Reason for Collection

The sample was collected as per memo for the FY 2008 Low Cost Generic Drug Sample Survey # 2008-800 (CP 7356.008) and is being reported in FACTS under Assignment # 896688 and Op # 3518061.

MFG Codes	Expiration Date
70664A1	Aug 2009

Firm Legal Name UDL Laboratories, Inc	Address 12720 Dairy Ashford Rd Sugar Land, TX 77478-2844 US	Type of Firm Shipper	Firm FEI 1610608	FCE
Actavis Totowa LLC	101 E Main St Little Falls, NJ 07424-5608 US	Manufacturer	2244683	
Wal-Mart Pharmacy Warehouse #6028	801 Corda Blvd Crawfordsville, IN 47933- 2152 US	Dealer	3004344335	
Size of Lot (b) (4) x 100 count bottles	Est. Value	Rept Type FDA484	Carrier Name	Date Shipped

Description of Sample

The sample consists of 2 x 100 count 0.25mg Digitek (Digoxin Tablets, USP) with NDC # 62794-146-01 and assigned lot # 706641A and expiry date 8/2009.

Method of Collection

2 x 100 count bottles of 0.25mg Digitek (Digoxin Tablets, USP) lot 70664A1 were randomly selected from shelf.

How Prepared

See continuation.

Collector's Identification on Package and/or Label
"Sample # 448892 EB 12/3/07"

Collector's Identification on Seal
"448892 Ernest Bizjak 12/3/07"

Sample Delivered To
FEDEX

Date Delivered 12/17/2007	Orig C/R & Records To DAL-DO
Lab w/Split Sample 0	Lab NRL

Document Number	Document Date	Document Type	Document Remarks
	12/03/2007	Other	FDA-482; 1 page
	12/03/2007	Other	FDA-484; 4 pages

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
	No Charge	No	No	Ernest Bizjak
Name of Signer		Date & Time of Signature		Meaning
Ernest Bizjak		12/14/2007	09:15 AM ET	Collector

Continuation:

Product Label

The white HDPE bottle with matching screw cap is labeled in part "NDC 62794-146-01 *** DIGITEK (digoxin tablets, USP) *** 250mcg (0.25 mg) *** 100 TABLETS *** Distributed by: BERTEK PHARMACEUTICALS INC. Sugar Land, TX 77478 *** Manufactured by: AMIDE PHARMACEUTICAL, INC. 101 East Main Street Little Falls, NJ 07424 USA *** Control No.: 70664A1 *** Exp. Date: Aug 09".

How Prepared

The 2 bottles were identified as per Collector's ID and placed into a clear Whirl-pak bag that was then officially sealed at the dealer. The sample was transported back to the DET-DO/INDY-RP where it was stored in a locked sample cabinet at ambient conditions until it was boxed and shipped to lab.

Remarks

Per assignment memo, test sample for UDU, Diss, and ID. All analytical methods are compendial.

Dena McClamroch, General Manager stated that she could not provide a dollar value for the sample. If this information is needed, contact Monty Mason, Pharmacy Director at ph#479-277-1558.